United States
Department of
Agriculture

Cooperative State
Research, Education,
and Extension Service

Competitive Programs

SBIR-03-1

Program Solicitation

Small Business Innovation Research Program

FY 2003

Phase I Closing Date: August 30, 2002
Phase II Closing Date: February 6, 2003

Telephone: (202) 401-4002
Internet: www.reeusda.gov/sbir

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E-mail: sbir@dbamlg.com
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Please note that the text of the proposal should be prepared using no smaller than 11 point font size regardless of whether it is single or double spaced.

The Program Solicitation, including all Application Forms, may be downloaded from the USDA SBIR Web Page: www.reeusda.gov/sbir

******PLEASE READ******

IMPORTANT CHANGES IN THE USDA SBIR FY 2003 PROGRAM SOLICITATION

Submission of Proposals - Proposals must be **received** at the USDA/CSREES/Proposal Services Unit by **close of business,** 5:00 p.m. Eastern Time, on the program deadline as indicated under Section 6.1.

New Topic Area - An additional topic area has been included in the FY 2003 Program Solicitation. **Topic Area 8.10, Wildlife,** focuses on developing new or improved technologies and environmentally sound approaches for the improved management of wildlife that will reduce the adverse impact of wildlife on agriculture and people and enhance the sustainability of wildlife populations.

Revised Topic Areas - Revisions have been made to the following topic areas: 8.2 Plant Production and Protection; 8.4 Air, Water and Soils; and 8.6 Rural and Community Development. In addition, proposals are encouraged that focus on problems dealing with bioterrorism and homeland security, especially as these issues relate to rural communities.

USDA'S PROGRAM SOLICITATION
SMALL BUSINESS INNOVATION RESEARCH
FISCAL YEAR 2003

1.0 GENERAL PROGRAM DESCRIPTION

1.1 Introduction

The U.S. Department of Agriculture (USDA) invites science-based small business firms to submit research proposals under this program solicitation entitled "Small Business Innovation Research Program, Fiscal Year 2003." Firms with strong scientific research capabilities in any of the topic areas described in section 8.0 are encouraged to participate. USDA will support high-quality research or research and development (R&D) proposals containing advanced concepts related to important scientific problems and opportunities that could lead to significant public benefit if the research is successful.

Objectives of the Small Business Innovation Research (SBIR) program include stimulating technological innovation in the private sector, strengthening the role of small businesses in meeting Federal research and development needs, increasing private sector commercialization of innovations derived from USDA-supported research and development efforts, and fostering and encouraging participation by women-owned and socially and economically disadvantaged small business firms in technological innovation. Questions of a general nature about this SBIR solicitation should be directed to:

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1.2 Three-phase Program

NOTE: **This program solicitation is primarily for the preparation and submission of Phase I proposals.** However, the solicitation is also applicable for those preparing Phase II proposals, for it contains the necessary forms for proposal submission, delineates the evaluation criteria that will be used, and provides other relevant information. More detailed guidance on Phase II proposal preparation will be provided by the Director, SBIR Program, in a letter that is sent out in the Fall of each year to Phase I awardees.

This program solicitation is issued pursuant to the Small Business Innovation Development Act of 1982, Pub. L. No. 97-219, as amended (15 U.S.C. 638) and Section 630 of the Act making appropriations for Agriculture, Rural Development, and Related Agencies' programs for fiscal year ending September 30, 1987, and for other purposes, as made applicable by Section 101(a) of Pub. L. No. 99-591, 100 Stat. 3341. This program is administered by the Cooperative State Research, Education, and Extension Service (CSREES) of the USDA.

This program is subject to the provisions found at 7 CFR Part 3403. These provisions set forth procedures to be followed when submitting grant proposals, rules governing the evaluation of proposals and the awarding of grants, and regulations relating to the post-award administration of grant projects.

The program will be carried out in three separate phases. Phase I is to determine the scientific or technical feasibility of ideas submitted by proposers on research topic areas described in section 8.0 of this solicitation with each award ranging up to $80,000 for a period normally not to exceed 6 months. The Phase I proposal should concentrate on research which will significantly contribute to **proving the scientific or technical feasibility** of the approach or concept and which would be a prerequisite to further USDA support in Phase II.

Phase II awards will be made during fiscal year (FY) 2003 to firms with approaches that appear sufficiently promising as a result of Phase I studies with each award ranging up to $300,000 for a period normally not to exceed 24 months. **Only those small businesses previously receiving Phase I awards in either FYs 2001 or 2002 are eligible to submit Phase II proposals in FY 2003.**

Please note, however, that for each Phase I project funded the awardee may apply for a Phase II award only once. Proposals for Phase II may only be submitted to the Federal agency from which the Phase I award was received.

Phase I awardees in FY 2002 who are unable to submit Phase II proposals for valid reasons during the FY 2003 funding cycle, will be eligible to apply for Phase II support no later than the FY 2004 funding cycle. One reason for not submitting the Phase II proposal during the FY 2003 funding cycle would be one which precludes completion of the Phase I project within the designated award period. In such instances, the awardee must request in writing, prior to the end of the Phase I grant period, a no-cost extension from the Authorized Departmental Officer, outlining the circumstances which prevent completion of the project. Once the no-cost extension request is approved, any remaining Federal funds may be expended on the project in accordance with the approved budget within the extended award period.

Phase II is the principal research or research and development effort and will require a more comprehensive application, outlining the proposed effort in detail. At the appropriate time, the Director of the SBIR Program will send a letter to all eligible Phase I awardees requesting Phase II proposals. The letter will provide instructions for preparing Phase II proposals and a deadline date (normally early February of each year) for submitting applications. USDA recognizes that Phase II awards may not be sufficient in either dollars or time for the firm to complete the total research and development required to bring the project results to commercialization in the market place. Therefore, completion of the research under these circumstances may have to be carried into Phase III, the commercialization phase.

See subsection 5.1 for estimated number of FY 2003 Phase I and Phase II awards and their established dollar limit.

The purpose of Phase III is to stimulate technological innovation and the national return on investment from research through the pursuit of commercialization objectives resulting from the USDA-supported work carried out in Phases I and II. No Federal SBIR funds may be used to support Phase III projects. However, firms are strongly encouraged to secure Phase III funding from their own resources or from other public and private sources of funds. Additionally, Phase III is to be conducted by the small business concern (including joint ventures and limited partnerships).

1.3 Follow-on Funding

In addition to supporting scientific research and development, another important goal of this program is to provide incentive and opportunity for small firms to convert USDA-sponsored research to technological innovation in the private sector. All proposed research should have some potential commercial outcome, and Phase II applicants are encouraged to obtain a contingent commitment for non-SBIR follow-on funding to pursue further development of the commercial potential during Phase III. Government funding pays for research relating to Federal objectives (Phases I and II); non-SBIR (public or private) funding pays for development of commercial objectives (Phase III).

Obtaining follow-on financial commitment(s) is the responsibility of the proposer. USDA understands that any such commitment will likely be contingent upon the Phase II awardee attaining technical objectives that are mutually agreed upon between the small business and the provider of the follow-on funding. These objectives should be closely related to those delineated in the Phase II research proposal. The technical objectives should be clearly defined and measurable, and should be specified in the commitment agreement at the threshold level that would justify such an investment. The objectives do not have to be identical to those stated in the Phase II proposal, but they must be able to be accomplished within the scope of the proposed SBIR-funded research. Any letters or other forms of tentative commitment for follow-on Phase III funding from sources other than Federal SBIR Programs, will be considered.

Phase I proposals should contain a brief description of any potential commercial application(s) and whether or not the small business will attempt to secure follow-on, non-SBIR funding to pursue the commercial development of the expected products from the proposed research. In order for Phase II proposers to receive consideration of follow-on funding during the review and evaluation process, a signed contingent commitment between the small business and the entity providing the follow-on financial support should be submitted with the Phase II application. While such commitment agreements are optional when submitting Phase II proposals, they will receive special consideration as a point of merit in the review and evaluation process where proposals are evaluated as being of approximately equal technical merit. **The maximum value (in Phase II evaluation) will be given for a signed formal agreement with reasonable terms and funding equal to or in excess of the Federal investment**

requested in the Phase II proposal. The agreement should set forth the specific amount of Phase III funds and should indicate the dates that such funds will be made available to the small business. Also, the agreement should contain a few specific technical objectives which, if achieved in Phase II, will make the commitment usable by the small business. The terms cannot be contingent upon the obtaining of a patent, due to the length of time this process requires.

The commitment may be in the form of venture capital or a package including venture capital, contract research and development, a joint venture, a research and development limited partnership, or other agreement with a non-SBIR source of funding. No amortization, repayment, or repurchase of commitment funds may be included during the Phase II period of performance.

Follow-on funding commitments will not be counted as part of the 50-page limit for Phase II proposals.

1.4 Eligibility and Limitations

Each organization submitting a proposal must qualify as a small business concern for research or research and development purposes, (see definitions in section 2.0).

A joint venture or a limited partnership is eligible to submit a proposal provided that the entity created qualifies as a small business concern in accordance with section (a)(2) of the Small Business Act, 15 U.S.C. 632, and the definition found at subsection 2.2 of this solicitation. **A joint venture must provide documentation confirming that it can act as a single legal entity for purposes of a grant awarded under the SBIR program.**

2.0 DEFINITIONS

The following definitions apply for purposes of this solicitation:

2.1 Research or Research and Development

Research or research and development (R&D) means any activity which is:

(A) A systematic, intensive study directed toward greater knowledge or understanding of the subject studied;

(B) A systematic study directed specifically toward applying new knowledge to meet a recognized need; or

(C) A systematic application of knowledge toward the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements.

2.2 Small Business Concern

A small business concern means a concern which **at the time of award** of the Phase I and Phase II funding agreements meets the following criteria:

(A) Is organized for profit, independently owned or operated, is not dominant in the field in which it is proposing, has its principal place of business located in the United States, has a number of employees not exceeding 500 (full-time, part-time, temporary, or other) in all affiliated concerns owned or controlled by a single parent concern, and meets the other regulatory requirements outlined in 13 CFR Part 121. Business concerns, other than licensed investment companies or State development companies qualifying under the Small Business Investment Act of 1958, 15 U.S.C. 661 et seq., are affiliates of one another when directly or indirectly (l) one concern controls or has the power to control the other; or (2) third parties (or party) control or have the power to control both. Control can be exercised through common ownership, common management, and contractual relationships. The term "affiliates" is defined in greater detail in 13 CFR 121.103. The term "number of employees" is defined in 13 CFR 121.106. Business concerns include, but are not limited to, any individual, partnership, corporation, joint venture, association, or cooperative.

(B) Is at least 51 percent owned or, in the case of a publicly owned business, at least 51 percent of its voting stock is owned by United States citizens or lawfully admitted permanent resident aliens.

(C) Is the primary source of employment of the project director of the proposed effort **at the time of**

award and during the conduct of the proposed research. Primary employment means that more than one-half of the project director's time is spent in the employ of the small business. Primary employment with the small business applicant precludes full-time employment with another organization. This requirement applies to both Phase I and Phase II awards. If the proposed project director is employed by another organization (e.g., university or another company) at the time of submission of the application, **documentation must be submitted with the proposal from the project director's current employer verifying that, in the event of an SBIR award, he/she will become a less than half-time employee of such organization and will remain so for the duration of the SBIR project.** While the project director must work more than one-half of his/her time for the small business during the entire grant period, there is no minimal time requirement for what percentage of project director's time is spent working on the proposed research.

(D) Is the primary performer of the proposed research effort. In Phase I, a minimum of **two-thirds** of the research or analytical work, as determined by budget expenditures, must be performed by the proposing organization. For **Phase II awards,** a minimum of **one-half** of the research or analytical effort must be conducted by the proposing firm. For both Phase I and Phase II the research must be performed in the United States. However, based on a rare and unique circumstance, for example, a supply or material or other item or project requirement that is not available in the United States, that particular portion of the research or research and development may be performed or obtained in a country outside of the United States with proper justification and USDA approval. **The space used by the SBIR awardee to conduct the research must be space over which it has exclusive control for the period of the grant.**

2.3 Project Director

The project director is an individual designated by the applicant to be principally responsible for the scientific or technical direction of the work described in a proposal. Therefore, the individual should have a scientific/technical background.

2.4 Socially and Economically Disadvantaged Small Business Concern

A socially and economically disadvantaged small business concern is one:

(A) Which is at least 51 percent owned by (i) an Indian tribe or a native Hawaiian organization, or (ii) one or more socially and economically disadvantaged individuals; and

(B) Whose management and daily business operations are controlled by one or more socially and economically disadvantaged individuals.

For purposes of this solicitation, a socially and economically disadvantaged individual is defined as a member of any of the following groups: Black Americans, Hispanic Americans, Native Americans, Asian-Pacific Americans, Subcontinent Asian Americans, other groups designated from time to time by the Small Business Administration (SBA) to be socially disadvantaged, or any other individual found to be socially and economically disadvantaged by the SBA. See sections 103, Who is Socially Disadvantaged?, and 104, Who is Economically Disadvantaged?, of 13 CFR Part 124.

Note: The certification of socially and economically disadvantaged small business at item 2 of Form CSREES-667 is for statistical purposes only.

2.5 Women-owned Small Business Concern

Women-owned small business concern means a small business concern that is at least 51 percent owned by a woman or women who also control and operate it. "Control" as used in this context means exercising the power to make policy decisions. "Operate" as used in this context means being actively involved in the day-to-day management of the concern.

Note: Certification of women-owned small business at item 3 of Form CSREES-667 is for statistical purposes only.

2.6 United States

United States means the 50 States, the territories and possessions of the United States, the Commonwealth of Puerto Rico, Guam, American Samoa, the Commonwealth of the Northern Marianas, the Virgin Islands of the United States, and the District of Columbia.

2.7 Program Solicitation

A program solicitation is a formal request for proposals whereby an agency notifies the small business community of its research or R&D needs and interests in selected areas and invites proposals from small business concerns in response to these needs and interests.

2.8 Subcontract

A subcontract is any agreement, other than one involving an employer-employee relationship, entered into by a Federal Government funding agreement awardee for supplies or services required solely for the performance of the original funding agreement.

2.9 Funding Agreement

A funding agreement is any contract, grant, or cooperative agreement entered into between any Federal agency and any small business for the performance of experimental, developmental or research work funded in whole or in part by the Federal Government.

2.10 Commercialization

Commercialization is defined as the process of developing markets and producing and delivering products or services for sale (whether by the originating party or by others); as used here, commercialization includes both government and commercial markets.

3.0 PROPOSAL PREPARATION INSTRUCTIONS AND REQUIREMENTS

3.1 Proposal Requirements

This is a solicitation for **Phase I research proposals on advanced concepts** from small businesses which have strong research capabilities in the basic and applied sciences.

The proposed research must be responsive to one of the USDA program interests stated in the research topic descriptions of this solicitation. The USDA does not prioritize between research topics or between different research objectives within a specific research topic. Thus, the specific research objectives proposed by applicants are investigator-initiated and not initiated by the USDA, and applicants are free to propose any research project that fits within one of the research topics listed in section 8.0. The same research can often be the basis for technological innovation, new commercial products, processes, or services which benefit the public. This is a desirable economic objective, and such proposals are encouraged.

Proposals must cover only scientific research activities. **A small business must not propose technical assistance, demonstration projects, classified research, or patent applications.** Many of the research projects supported by the SBIR program lead to the development of new products based upon the research results obtained during the project. However, projects that seek funding solely for product development where no research is involved, i.e., the funds are needed to permit the development of a product based on previously completed research, will not be accepted.

Literature surveys should be completed prior to the Phase I or Phase II submission of the proposal and should not be proposed as part of the R&D effort. Proposals that deal principally with developing proven concepts for commercial markets or scaling up previously developed prototypes for commercial production should not be submitted, since such efforts are considered the responsibility of the private sector and therefore are not supported by USDA. **A proposal must be limited to only one topic,** the title of which must be entered on the Proposal Cover Sheet, Form CSREES-667, of the application. The same proposal may not be submitted under more than one topic. However, an organization may submit separate proposals on different topics or different proposals on the same topic under this solicitation. Where similar research is discussed under more than one topic, the proposer should choose that topic whose description appears most relevant to the proposer's research concept. Proposers may respond to any of the topics listed under section 8.0. Research may be carried out through the construction and evaluation of a laboratory prototype, where necessary. **Duplicate proposals will be returned to the applicant without review.**

The purpose of a research proposal is to provide a written statement that contains sufficient information to persuade members of the research community who review the proposal and then advise the USDA SBIR professional staff that the proposed research is a sound approach to an important scientific question and is worthy of support under the stated USDA evaluation criteria (see section 4.0). The proposal should be self-contained and written

with the care and thoroughness accorded papers for publication. Each proposal should be reviewed carefully by the applicant and by others knowledgeable on the subject to ensure inclusion of data essential for comprehensive evaluation.

3.2 General Content

This solicitation is designed to reduce the investment of time and cost to small business concerns in preparing formal proposals. Those who wish to respond should submit a research proposal of **no more than 25 pages (50 pages for Phase II**), including cover page, project summary page, budget pages, and all proposal-related enclosures or attachments unless otherwise stated.

The following items do not count as part of the 25-page limit for Phase I or 50-page limit for Phase II: 1) Table of Contents (see subsection 3.3 (C)); 2) Response to Previous Review (see subsection 3.3(D)); 3) Assurance Statement(s) (see subsection 3.3(O)); 4) National Environmental Policy Act Exclusions Form (see subsection 3.3(P)); 5) letters from consultants, subcontractors or cooperative research and development agreement (CRADA) cooperators (see subsection 3.3(H)); **vitae for these individuals, however, are part of the page limit**; 6) letter from a university describing the arrangement if university facilities are being used (see subsection 3.3(G)); 7) follow-on funding agreements for Phase II proposals (see subsection 1.3); 8) documentation of multiple Phase II awards to be submitted with Phase I proposals if the applicant has received more than 15 Phase II awards during the preceding five fiscal years (see subsection 3.3(M)).

The text must be prepared on only one side of the page using standard size (8 ½" x 11"; 21.6 cm x 27.9 cm) white paper, with margins not less than one inch on all sides and **no type smaller than 11 point font size regardless of whether it is single or double spaced.** In the interest of equity to all proposers, no additional attachments, appendixes, or references beyond the 25-page limitation for Phase I (50-page limitation for Phase II) will be considered in the proposal evaluation process, and proposals in excess of the page limitation will not be considered for review or award. In addition, supplementary materials, **revisions,** and/or substitutions **will not be accepted after the due date for proposals**.

It is not necessary to provide a lengthy discourse on commercial applications in the Phase I proposal except to discuss them briefly under subsection 3.3(E), as appropriate, as well as under subsection 3.3(J). The Phase I proposal must be principally directed at feasibility-related research or R&D on the specific topic chosen.

3.3 Proposal Format

The following instructions apply for both Phase I and II proposals, unless otherwise noted. **Phase II proposals may only be submitted by Phase I award winners as noted in section 1.2.**

Note: The application forms may be downloaded from the USDA SBIR web page: www.reeusda.gov/sbir. The forms are available in Word, WordPerfect, and PDF format.

(A) **Proposal Cover Sheet** - Complete Form CSREES-667 and use it as page 1 of the proposal. **All pages must be consecutively numbered.** The original of the Proposal Cover Sheet must contain the pen-and-ink signatures of the proposed project director and the authorized organizational official. A proposal which does not contain the required signatures may be returned to the proposing small business without review. All other copies of the proposal must also contain a proposal cover sheet but facsimile or photocopied signatures will be accepted. The title should be a brief (140-character maximum), clear, specific designation of the research proposed. It will be used to provide information to Congress and also will be used in issuing press releases; it should not contain highly technical words. In addition, phrases such as "investigation of" or "research on" should not be used.

(B) **Project Summary** - Complete Form CSREES-668 and use it as page 2 of the proposal. The technical abstract, limited to 200 words, should include a brief description of the problem or opportunity, project objectives, and a description of the effort. Anticipated results and potential commercial applications of the proposed research also should be summarized in the space provided. Key words, to be provided in the last block on the page, should characterize the most important aspects of the project.

The information contained on Form CSREES-668, "Project Summary," of successful proposals will be published by USDA and, therefore, should not contain proprietary information.

(C) **Table of Contents** - A Table of Contents, itself unpaginated, should be placed immediately following the Project Summary, Form CSREES-668. This table should direct the reviewer to the pages for all sections of the proposal, beginning with the Proposal Cover Sheet.

(D) **Resubmitted Proposals** (Phase I)- If you are submitting a proposal in which the project described was previously submitted to the SBIR program but not funded, state the proposal is a resubmission on Question 10 of the Proposal Cover Sheet, Form CSREES-667. The revised proposal should clearly indicate the changes that have been made in the project. A clear statement acknowledging comments of the previous review, indicating revisions, rebuttals, etc., is part of the evaluation criteria as noted in subsection 4.3(F). Proposals that are resubmissions **must** respond to the previous submission's panel summary on no more than one page, titled "**RESPONSE TO PREVIOUS REVIEW**," which is to be placed directly after the Table of Contents. This section will not be counted within the page limitations of the proposal. (Refer to subsection 4.2(I) Initial Screening Criteria.)

(E) **Technical Content** - Begin the main body of the proposal on page 3 and include:

(1) **Identification and Significance of the Problem or Opportunity** - Clearly state the specific technical problem or opportunity addressed and its importance.

(2) **Background and Rationale** - Indicate the overall background and technical approach to the problem or opportunity and the part that the proposed research plays in providing needed results.

(3) **Relationship with Research or Research and Development**

(**Phase I**) - Discuss the significance of the Phase I effort in providing a foundation for the Phase II R&D effort. State the anticipated results of the approach if the project is successful. This should address: (a) the technical, economic, social, and other benefits to the Nation and to users of the results such as the commercial sector, the Federal Government, or other researchers; (b) the estimated total cost of the approach relative to benefits; and (c) any specific policy issues or decisions which might be affected by the results.

Phase II - Discuss the results of the Phase I project. Include a discussion of the overall background of the Phase I project, a list of the Phase I technical objectives, a presentation of a detailed description of the Phase I results, a clear interpretation of the results, and conclusions as to the feasibility of the project. This section is where the Phase II applicant presents results from Phase I that establishes technical feasibility. Therefore, this section should provide an adequate discussion of Phase I results.

(4) **Technical Objectives** - State the specific objectives of the research or research and development effort. For Phase I, include the technical questions needed to establish the technical feasibility of the proposed approach.

(5) **Work Plan** - The work plan must provide an explicit, detailed description of the research or research and development approach. The plan should list the tasks to be performed, **provide details of the methodology that would be used to research each task**, including statistical analysis, if applicable, and indicate how and where the work will be carried out. The Phase I effort should attempt to determine the technical feasibility of the proposed concept. The work plan should be linked with the technical objectives of the research and the questions the effort is designed to answer. **This section should constitute a substantial portion of the total proposal.**

(6) **Related Research or Research and Development** - Describe significant research or R&D activities from relevant literature that are directly related to the proposed effort, including any conducted by the project director or by the proposing small business, how the proposed effort expands on the related work, and any planned coordination with outside sources. **The proposer must persuade reviewers that he or she is aware of related research in the selected subject.** It is critical that the applicant make a convincing case that the proposed research builds upon previous research and, if successful, will lead to the development of new technology or a substantial improvement of existing technology.

(7) **References** - Provide a complete list of all references cited in the proposal. For each reference, provide the complete name for each author, the date of the publication, the full title of the article, name of the journal or book published and the page numbers. The references should be listed in alphabetical order using the last name of the first author.

(F) **Key Personnel and Bibliography** - Identify key personnel of the small business concern and include information on their directly related education and experience or a current copy of their vitae. (For consultants and subcontractors, include this information under subsection 3.3 (H). For each key person, provide a chronological list of the most recent representative publications in the topic area during the preceding five years, including those in press. List the authors (in the same order as they appear on the paper), the full title, and the complete reference as specified in subsection 3.3 (E)(7). Where vitae are extensive, efforts should be made to reduce them to one page by focusing on only the most relevant experience or publications in order to meet the proposal limitation.

(G) **Facilities and Equipment** - Describe the types, location, and availability of instrumentation and physical facilities necessary to carry out the work proposed. Items of equipment to be purchased must be fully justified under this section. When purchasing equipment or a product under the SBIR funding agreement, the small business should purchase only American-made items whenever possible. **If university facilities are being used, there must be a letter in the proposal from the authorized organizational representative of the university describing the arrangement and testifying that the facilities will be subject to the exclusive use and control of the applicant.** These letters will not be considered a part of the page limitation.

(H) **Outside Services** - Involvement of university or other outside personnel in the planning and research stages of the project as consultants or through subcontracting arrangements is permitted and may be particularly helpful to small firms that have not previously received Federal research awards. Establishment of a CRADA with a USDA laboratory or other Federal laboratory may also be beneficial to proposing firms. If the proposal involves outside consultants, subcontracts or involvement with a CRADA partner, these arrangements should be described in detail. Include a brief resume and listing of relevant publications for each consultant and subcontractor. **Proposals must include letters from proposed consultants, subcontractors or CRADA cooperators indicating their willingness to serve in order for such participation to be considered during the proposal review and evaluation process (see subsection 4.3(C) or 4.5(D), as appropriate).** These letters will not be considered a part of the page limitation.

(I) **Satisfying the Public Interest** - Specify how the proposed research will satisfy one or more of the following objectives: (1) Develops sustainable agricultural production systems; (2) Protects natural resources and the environment; (3) Creates a safe, nutritious and affordable food supply; (4) Develops value-added food and non-food products from agricultural materials; (5) Enhances global competitiveness; and (6) Enhances economic opportunity and quality of life, especially for people in rural areas.

(J) **Potential Post Application** - Briefly describe the commercialization potential of the proposed research in Phase I. In Phase II commercialization potential is more important; therefore, this section should be more extensive in a Phase II proposal. In addition, indicate whether there appears to be a potential use of the proposed research by the Federal Government. Include a brief description of the proposing company (e.g., date founded, number of employees) and its field of interest. What are the major competitive products in this field, and what advantages will the proposed research have over existing technology (in application, performance, technique, efficiency or cost).

(K) **Current and Pending Support** - If a proposal, substantially the same as the one submitted in response to this solicitation, has been previously funded or is currently funded, pending, or about to be submitted to another Federal agency or to USDA in a separate action, the proposer must provide the following information:

(1) Name and address of the agency(s) to which a proposal was submitted, or will be submitted, or from which an award is expected or has been received.

(2) Date of actual or anticipated proposal submission or date of award, as appropriate.

(3) Title of proposal or award, identifying number assigned by the agency involved, and the date the proposal was submitted or the award was received.

(4) Applicable research topic area for each proposal submitted or award received.

(5) Title of research project.

(6) Name and title of project director for each proposal submitted or award received.

USDA will not make awards that duplicate research funded (or to be funded) by other Federal agencies.

(L) **Budget** - Complete Form CSREES-2004 only for the **phase under which you are currently applying**. (An applicant for Phase I funding should not submit both Phase I and Phase II budgets.) Please note the following in completing the budget: It will be necessary to include a budget narrative with supporting detail for each budget category as noted in items (1) through (5) of this subsection. The narrative should be included on a separate sheet of paper and placed immediately behind Form CSREES-2004. A separate Form CSREES-2004 must be submitted for any subcontract included in "All Other Direct Costs" of the applicant's budget form.

(1) **Salaries and Wages** - Indicate the number and kind of personnel for whom salary support is sought, including job tasks. For key personnel, also indicate the number of work months of involvement to be supported with USDA funds (see section labeled "CSREES Funded Work Months"), and explain how the level of compensation was established, e.g., the hourly rate of pay, the monthly rate of pay, or the yearly rate of pay.

(2) **Equipment** - Performing organizations are expected to have appropriate facilities, suitably furnished and equipped. However, funding for items of equipment may be requested provided that they are specifically identified with the dollar amount and adequately justified (see item (E) of this section), **but such requests should normally not exceed 10% of the budget for Phase I**. This limit does not apply to Phase II budgets. Equipment is defined as an article of nonexpendable, tangible personal property having a useful life of more than 1 year and an acquisition cost of $5000 or more per unit. However, consistent with recipient policy, lower limits may be established. **Vesting** of title to equipment purchased with funds provided under an SBIR funding agreement will be **determined by USDA. Awardees should plan to lease expensive equipment.** The inclusion of equipment will be carefully reviewed with respect to need and appropriateness for the research proposed.

(3) **Materials and Supplies** - The types of expendable materials and supplies required should be indicated in general terms with estimated costs.

(4) **Travel** - The type and extent of travel and its relationship to the project should be specified. Funds may be requested for field work or for travel to professional meetings. Phase I requests for foreign travel are discouraged but may be approved (e.g., proposals submitted to the Marketing and Trade topic area that are focused on export issues) based on the justification provided in the proposal. The inclusion of foreign travel in Phase II will be carefully reviewed with respect to need and appropriateness for the research proposed. In the budget narrative, for travel, provide the purpose, the destination, method of travel, number of persons traveling, number of days, and estimated cost for each trip. If details of each trip are not known at the time of proposal submission, provide the basis for determining the amount requested.

(5) **All Other Direct Costs** - Other anticipated direct costs not included above should be itemized. Examples include, but are not limited to, subcontracts and consultants. See subsections 3.3(H) for required documentation associated with subcontracts and consultants. A budget and budget narrative stating subcontractual and consulting costs and the rationale for the amount of the costs is required.

(6) **Fee** - A reasonable fee, not to exceed 7% of total Federal funds awarded (.07527 of total Direct and F&A/Indirect Costs) is permitted under this program solicitation but proposers are encouraged to minimize fee requests due to the small amount

of funds available. **All fees are subject to negotiation with USDA.** If a fee is requested, the amount should be indicated in block M., "Other," on the budget sheet.

(7) **Indirect Costs** - If available, the current rate negotiated with the cognizant Federal negotiating agency should be used. Indirect costs may not exceed the negotiated rate. If a negotiated rate is used, the percentage and base should be indicated in the space allotted under item K. on the budget sheet. If no rate has been negotiated, a reasonable dollar amount in lieu of indirect costs may be requested, which will be subject to approval by USDA. In the latter case, if a proposal is recommended for funding, an indirect cost rate proposal must be submitted to support the amount of indirect costs requested. CSREES will request an indirect cost rate proposal and provide instructions, as necessary. A proposer may elect not to charge indirect costs and, instead, use all grant funds for direct costs. If indirect costs are not charged, the phrase "None requested" should be written in this space.

(8) **Cost Sharing** - Cost sharing is permitted for proposals under this program solicitation; however, cost sharing is not required nor will it be an evaluation factor in considering the competitive merit of proposals submitted.

(M) Documentation of Multiple Phase II Awards

(1) A small business concern that submits a proposal for a funding agreement for Phase I of an SBIR Program and that has received more than 15 Phase II SBIR awards during the preceding 5 FYs must document the extent to which it was able to secure third phase funding to develop concepts resulting from previous second phase SBIR awards. In addition, the documentation must include the name of the awarding agency, date of award, funding agreement number, amount, topic or subtopic title, follow-on agreement amount, source and date of commitment and current commercialization status for each Phase II. (This information will not be counted toward the 25-page limitation.); and

(2) USDA shall collect and retain the information submitted under subparagraph (M)(1) at least until the General Accounting Office submits the report required under section 105 of the Small Business Research and Development Enhancement Act of 1992.

(N) **Certifications Regarding Non-Delinquency on any Federal Debt, Drug-free Workplace, Debarment and Suspension, and Lobbying** - Certifications are accomplished by signing Form CSREES-667, Proposal Cover Sheet. (For instructions see subsection 5.11(A) through (D).)

(O) **Assurance Statement(s)** - See subsection 5.8. Complete Form CSREES-2008 as appropriate. This form will not be considered a part of the page limitation.

(P) **National Environmental Policy Act Exclusions Form (NEPA)** - See subsection 5.11(E). Complete Form CSREES-2006 and place it at the end of the proposal. This form will not be considered a part of the page limitation.

4.0 METHOD OF SELECTION AND EVALUATION CRITERIA

4.1 Introduction

Phase I and Phase II proposals will be judged competitively in a two-stage process, based primarily upon scientific or technical merit. First, each proposal will be screened by USDA scientists to ensure that it is responsive to stated requirements contained in this solicitation (see subsection 4.2). Proposals found to be responsive will be technically evaluated by peer scientists knowledgeable in the appropriate scientific field using the criteria listed in subsection 4.3 or subsection 4.5, as appropriate. Each proposal will be judged on its own merits. **Unsolicited proposals or proposals not responding to research topic areas outlined in section 8.0 of this program solicitation are not eligible to be considered for a Phase I SBIR award and, hence, will be returned to the proposing firm without review.**

External peer reviewers will be used during the technical evaluation stage of this process. Selections will be made from among recognized specialists who are uniquely qualified by training and experience in their

respective fields to render expert advice on the merit of proposals received. It is anticipated that these experts will be drawn from universities, Government, and non-profit research organizations. If possible, USDA intends that peer review groups shall be balanced with minority and female representation and with an equitable age distribution.

Final decisions will be made by USDA based upon the ratings assigned by reviewers and consideration of other factors, **including the potential commercial application,** possible duplication of other research, any critical USDA requirements, program balance, budget limitations and, for Phase II proposals only, any follow-on funding commitment. There is no commitment by USDA to fund any particular proposal, to support any specific number of proposals in a given research topic area, or to make a specific number of awards under either Phase I or Phase II. USDA also may elect to fund several or none of the proposed approaches to the same topic. Care will be taken to avoid actual and potential conflicts of interest among reviewers. Evaluations will be confidential to USDA staff members, peer reviewers, and the proposed project director, to the extent permitted by law.

4.2 Initial Screening Criteria

To avoid misunderstanding, applicants should be aware that **proposals not satisfying all of the screening criteria may be returned to the proposing entity without review. Returned proposals may not be resubmitted** (with or without revision) **under this solicitation.** The initial screening criteria are the following:

(A) The proposing firm must qualify as a small business concern as defined in subsection 2.2.

(B) The proposal must meet the General Content requirements as described in subsection 3.2.

(C) Proposals must be limited to one topic (see subsection 3.1).

(D) The proposed budget must be within the dollar limit identified in subsection 1.2.

(E) The proposed duration of Phase I projects should normally not exceed 6 months, except in special, justified circumstances, and the duration of Phase II projects should normally not exceed 24 months. Where a proposed research project requires more than 6 months to complete in Phase I, a longer grant period, not to exceed 18 months, may be considered. A proposer of a Phase I project with an anticipated duration beyond 6 months should specify and justify the length of duration in the proposal at the time of its submission to USDA in order for it to be considered.

(F) Proposals must cover scientific research activities only (see subsection 3.1).

(G) The proposed Phase I research must fall within a solicited topic area. (See section 8.0 for the listing of research topic descriptions.)

(H) A proposal must contain adequate scientific/technical information to state clearly the research plan and objectives. **USDA reserves the right not to submit for review any proposal which it finds to have insufficient scientific/technical information.**

(I) A proposal must address concerns of the previous review panel. **USDA reserves the right not to submit for review any proposal found not to be responsive to the previous review.**

4.3 Phase I Evaluation Criteria

USDA plans to select for award those proposals offering the best value to the Nation. The primary evaluation criteria used by reviewers are listed below. Approximately equal consideration will be given to each criterion, **except for item (A) which will receive twice the value of any of the other items:**

(A) Scientific and Technical Feasibility: Is there a thorough background section with an up-to-date literature review? Are the stated objectives logical and will they lead toward proving the technical feasibility of the approach or concept? Does the research plan offer an original and innovative approach to the problem and sufficient detail to indicate how each research objective will be investigated? Can the research plan reasonably be completed in the requested grant period?

(B) Importance of the Problem: Does the proposal provide sufficient justification for the importance of the problem and clearly indicate the anticipated commercial potential of the proposed research? Is the proposed project in the public interest by satisfying one or more of the technical objectives listed in subsection 3.3 (I)?

(C) **Investigator and Resource Qualifications:** Is adequate bibliographic information provided to document that the project director, other key staff, and any consultants have the appropriate training and experience to carry out the proposed research plan? Is it clear that the project director will work a minimum of 51 percent of his/her time for the small business during the period of the grant and that the small business will conduct a minimum of two-thirds of the research effort? If consultants, subcontractors or CRADA cooperators are involved in the project are letters from these individuals included in the proposal verifying their willingness to participate in the research study? Are adequate research facilities available that the small business either owns or controls for the duration of the grant? Is adequate instrumentation available for the proposed research plan?

(D) **Budget:** Is the budget appropriate for the proposed research plan? Is sufficient budget detail provided to indicate clearly how the funds would be utilized?

(E) **Duplication:** Does the proposed research substantially duplicate any ongoing or previous research by the small business or by other researchers? Does the proposal clearly indicate how the proposed technology would differ significantly from existing technology? If the small business or a consultant has received or applied for patent(s) pertaining to the proposed technology, does the proposed research constitute a legitimate feasibility study?

(F) **Resubmission:** If the proposal is a resubmission, did the applicant provide a "Response to Previous Review?" Were the responses to the previous year's panel summary appropriate? (Refer to subsection 3.3(D), Proposal Format.)

4.4 Phase I Review Process

USDA uses confidential peer review as the basis for evaluating all Phase I proposals. There are separate review panels corresponding to each of the topic areas listed in Section 8.0. (The Plant Production and Protection topic area is subdivided into Biology and Engineering review panels). All reviewers are drawn primarily from universities, government, and non-profit research organizations. For each topic area a leading research scientist is appointed as a topic manager. In consultation with the SBIR program staff, this individual appoints a review panel. The review panel meets in Washington, D.C., to evaluate all proposals. Proposals are reviewed both by members of the review panel and by ad hoc reviewers with specific expertise appropriate for each proposal. The panel discusses each proposal carefully and then ranks the proposals. The panel rankings are used in determining which proposals are funded.

Considerable effort is made to ensure that the review process is confidential. All reviewers are instructed to handle all proposals in complete confidence. Under the reviewer's signature on the review sheet the following sentence appears: "The reviewer whose signature appears above agrees to treat the contents of this proposal as confidential and that no basis for a conflict-of-interest has been found."

Every effort is made to avoid even the appearance of a conflict-of-interest (COI). The USDA has very detailed rules on COI that are followed during the review process. If a panel member has a COI on a proposal, he/she is excused from the panel meeting while the particular proposal is being discussed. USDA is committed to ensuring the review process is fair and is handled with confidence.

4.5 Phase II Evaluation Criteria

A Phase II proposal may be submitted **only** by a USDA Phase I awardee. The primary evaluation criteria used by reviewers are listed below and except for item (B) are largely identical to those for Phase I. Approximately equal consideration will be given to each criterion, **except for items (A) and (B) which will receive twice the value of any of the other items:**

(A) **Scientific and Technical Feasibility:** Is there a thorough background section with an up-to-date literature review? Are the stated objectives logical and appropriate for a two year research and development period? Does the research plan offer an original and innovative approach to the problem and sufficient detail to indicate how each research objective will be investigated?

(B) **Degree to Which Phase I Objectives were Met and Technical Feasibility Established:** Are the Phase I objectives clearly stated and Phase I results presented in sufficient detail to permit a reviewer to determine whether the objectives were fully met and technical feasibility clearly established?

(C) **Importance of the Problem:** Does the proposal provide sufficient justification for the importance of

the problem and clearly indicate the anticipated commercial potential of the proposed research? Is the proposed project in the public interest by satisfying one or more of the technical objectives listed in subsection 3.3(I)?

(D) **Investigator and Resource Qualifications:** Is adequate bibliographic information provided to document that the project director, other key staff, and any consultants have the appropriate training and experience to carry out the proposed research plan? Is it clear that the project director will work a minimum of 51 percent of his/her time for the small business during the period of the grant and that the small business will conduct a minimum of one-half of the research effort? If consultants, subcontractors or CRADA cooperators are involved in the project are letters from these individuals included in the proposal verifying their willingness to participate in the research study? Are adequate research facilities available that the small business either owns or controls for the duration of the grant? Is adequate instrumentation available for the proposed research plan?

(E) **Budget:** Is the budget appropriate for the proposed research plan? Is sufficient budget detail provided to indicate clearly how the funds would be utilized?

(F) **Duplication:** Does the proposed research substantially duplicate any ongoing or previous research by the small business or by other researchers? Does the proposal clearly indicate how the proposed technology would differ significantly from existing technology? If the small business or a consultant has received or applied for patent(s) pertaining to the proposed technology, does the proposed research constitute a legitimate feasibility study?

In the event that two or more proposals are of approximately equal merit, a follow-on funding commitment for continued development in Phase III will be an important consideration. The value of any commitment will depend upon the degree of commitment made by non-Federal investors, with the **maximum value resulting from a signed agreement with reasonable terms for an amount at least equal to the funding requested from USDA in Phase II.**

4.6 Phase II Review Process

USDA uses confidential peer review as the basis for evaluating all Phase II proposals. All reviewers are drawn primarily from universities, government, and non-profit research organizations. However, there are far fewer proposals at Phase II and a different process is used. There are no review panels. Instead, six to eight top experts for each proposal are contacted to secure their agreement to serve as an ad hoc reviewer. A proposal is not sent to a reviewer unless he/she agrees to review the proposal in strict confidence. In addition, under the reviewer's signature on the review sheet the following sentence appears: "The reviewer whose signature appears above agrees to treat the contents of this proposal as confidential and no basis for a conflict-of-interest has been found." The same COI rules used in the Phase I are used for Phase II and no individual is sent a proposal where even the appearance of a COI exists.

4.7 Notice to Proposers

Technical reviewers will base their conclusions and recommendations on information contained in the proposal. It cannot be assumed that reviewers are acquainted with any experiments referred to within a proposal, with key individuals, or with the small business itself.

After final decisions have been announced, a panel summary that briefly sets forth the main strengths and weaknesses of the proposal, plus written reviews of the proposal, will be sent to the proposed project director. The reviews will not include the scores or the identities of the reviewers. Due to funding limitations and USDA's desire to support as many worthwhile projects as possible, it may be necessary for USDA to reduce the amount of an award below the amount requested by a small business (or to fund only certain objectives outlined in the proposal). Any significant changes will be discussed with the proposing firm, which may then be asked to submit a revised budget reflecting the reduced amount. In the event that this occurs, specific instructions will be provided to the proposer.

5.0 CONSIDERATIONS

5.1 Awards

USDA expects to make approximately 90 Phase I awards ranging up to $80,000 each to small businesses in FY 2003, depending upon the availability of funds. Awards are expected to be made on or before May 15, 2003. USDA will announce the names of those concerns receiving awards, and successful proposers will then normally have 6 months after awards are made to carry out their proposed Phase I effort.

USDA expects to make approximately 35 Phase II awards ranging up to $300,000 each to previous USDA Phase I awardees, depending upon the results of the Phase I efforts, the scientific and technical merit of the Phase II proposal, and the availability of funds.

In accordance with the guidelines contained in 31 U.S.C. 6301-6308, and the authority contained in Section 630 of the Act making appropriations for Agriculture, Rural Development, and Related Agencies' programs for fiscal year ending September 30, 1987, and for other purposes, as made applicable by Section 101(a) of Public Law Number 99-591, 100 Stat. 3341, **all Phase I and Phase II awards will be issued as research grants.**

5.2 Reports

For both Phase I and Phase II an original and two copies of a brief interim progress report must be submitted at approximately the mid-point in the project. In addition, an original and two copies of a comprehensive final performance report must be submitted within 30 days following expiration of the Phase I grant and within 90 days following expiration of the Phase II grant. The report should include a single-page project summary as the first page. This summary should include the purpose of the research, a brief description of the research carried out, the research findings or results, and, in a final paragraph, potential applications (commercial or other) of the research. The balance of the report should include a comparison of actual accomplishments with the goals established for the grant; the reasons for slippage if established goals were not met; estimates of technical feasibility; and additional pertinent information such as an explanation of cost over-runs or unexpectedly high unit costs. Also, identify all other recipients (public and private) of the research results documented in the Phase I or Phase II report. This report should be submitted to Dr. Charles F. Cleland, Director, SBIR Program (see subsection 1.1 for address, telephone, and facsimile numbers).

A final "Financial Status Report" (SF-269) is due within 90 days after the expiration date of the grant and should be submitted to the Funds Management Branch, Office of Extramural Programs at the address listed below, in accordance with instructions contained in Section 3015.82 of the Uniform Federal Assistance Regulations.

Funds Management Branch
Office of Extramural Programs
Cooperative State Research, Education, and Extension Service
U.S. Department of Agriculture
STOP 2298
1400 Independence Avenue, S.W.
Washington, D.C. 20250-2298
Telephone: (202) 401-4527

5.3 Payment Schedules

Payments will be made to the recipient by electronic transfer. The frequency of payment as well as required forms and pertinent submission instructions for each project will be provided to the small business concern when the funding agreement is forwarded to it for acceptance.

5.4 Proprietary Information

If a proposal contains proprietary information that constitutes a trade secret, proprietary commercial or financial information, confidential personal information, or data affecting the national security, it will be treated in confidence to the extent permitted by law, provided the information is clearly marked by the proposer with the term "confidential proprietary information," is confined to a separate page or pages, and provided the following legend also appears in the designated area at the bottom of the proposal's cover sheet (Form CSREES-667):

> The following pages (specify) contain proprietary information which (name of proposing organization) requests not be released to persons outside the Government, except for purposes of evaluation.

USDA, by law, is required to make the final decision as to whether the information is required to be kept in confidence. Information contained in unsuccessful proposals will remain the property of the proposer. However, USDA will retain for one year one file copy of all proposals received; extra copies will be destroyed. Public release of information for any proposal submitted will be subject to existing statutory and regulatory requirements. The legislation reauthorizing the SBIR Program strengthened the protection of awardee firms relative to maintaining confidentiality of proprietary information for a period of four years after the end of the grant period. However, any proposal which is funded will be considered an integral part of the award and normally will be made available to the public upon request through the Freedom of Information Act, except for designated proprietary information.

The inclusion of proprietary information is discouraged unless it is necessary for the proper evaluation of the proposal. If proprietary information is to be included, it should be limited, set apart from other text on a separate page, and keyed to the text by numbers. It should be confined to a few critical technical items which, if disclosed, could jeopardize the obtaining of foreign or domestic patents. Trade secrets, salaries, or other information which could jeopardize commercial competitiveness should be similarly keyed and presented on a separate page. Proposals or reports which attempt to restrict dissemination of large amounts of information may be found unacceptable by USDA. **Any other legend than that listed in the first paragraph of this section may be unacceptable to USDA and may constitute grounds for return of the proposal without further consideration.** Without assuming any liability for inadvertent disclosure, USDA will limit dissemination of such information to its employees and, where necessary for the evaluation of the proposal, to outside reviewers on a confidential basis. Since technical reports by the project director may be made available to the public, such reports shall not contain any restrictive language purporting to limit their use other than that which is set off on a proprietary page. However, USDA, to the extent permitted by law, normally will honor a request to delay release of the report for 6 months, or longer if reasonable, so the proposer may seek patent protection or follow-on-funding where appropriate.

5.5 Rights in Technical Data

Rights in technical data, including software developed under the terms of any funding agreement resulting from a proposal submitted in response to this solicitation, shall remain with the grantee. However, the Government shall have the limited right to use such data for Governmental purposes and shall not release such data outside the Government without permission of the grantee for a period of four years from completion of the project under which the data were generated. Effective at the conclusion of the four-year period, the Government shall retain a royalty-free license for Governmental use of any technical data delivered under the agreement, whether patented or not.

5.6 Copyrights

With prior written permission of the Authorized Departmental Officer, the grantee normally may copyright and publish (consistent with appropriate national security considerations, if any) material developed with USDA support. USDA receives a royalty-free license for the Federal Government and requires that each publication contain the following acknowledgment and disclaimer statement:

> "This material is based upon work supported by the U.S. Department of Agriculture under Grant No. (awardee should enter agreement number here). Any opinions, findings, and conclusions or recommendations expressed in this publication are those of the author(s) and do not necessarily reflect the views of the U.S. Department of Agriculture."

The last sentence may be omitted from articles published in scientific journals.

5.7 Patents and Inventions

Allocation of rights to inventions shall be in accordance with 35 U.S.C. 202-206 and the Department of Commerce implementing regulations entitled "Rights to Inventions Made by Nonprofit Organizations and Small Business Firms under Government Grants, Contracts and Cooperative Agreements" at 37 CFR Part 401. These regulations provide that small businesses normally may retain the principal worldwide patent rights to any invention developed with USDA support. USDA receives a royalty-free license for Federal Government use, reserves the right to require the patentee to license others in certain circumstances, and requires that anyone exclusively licensed to sell the invention in the United States must normally manufacture it domestically. To the extent authorized by 35 U.S.C. 205, USDA will not make public any information disclosing a USDA-supported invention for a four-year period to allow the grantee a

reasonable time to file an initial patent application. Additional information may be obtained by contacting:

Mr. M. Howard Silverstein
Deputy Assistant General Counsel for Patents
U.S. Department of Agriculture
STOP 1415
1400 Independence Avenue, S.W.
Washington, D.C. 20250-1415

5.8 Research Involving Special Considerations

A number of situations frequently encountered in the conduct of scientific research require the submission of special information for a particular project. Since some types of research targeted for SBIR support have high probability of involving either recombinant deoxyribonucleic acid (DNA) molecules, human subjects at risk, or vertebrate animals, special instructions follow.

If the proposed research will involve either recombinant DNA molecules, human subjects at risk, or vertebrate animals, the proposal must so indicate by checking "Yes" in Item 9. of Form CSREES-667 and then completing Form CSREES-2008. Further, in the event that the project is funded, the proposer may be required to have the research plan reviewed and approved by the appropriate review board or committee. It is suggested that proposers contact local universities, colleges, or nonprofit research organizations which have established such reviewing mechanisms to have this service performed.

Guidelines to be applied and observed when conducting such research are outlined below.

(A) **Recombinant DNA Molecules** - The performing organization is required to comply with the guidelines established by the National Institutes of Health entitled, Guidelines for Research Involving Recombinant DNA Molecules. In the event a project involving recombinant DNA or RNA molecules results in a grant award, a qualified Institutional Biosafety Committee must approve the research before funds will be released.

(B) **Human Subjects at Risk** - Regulations issued by the Department of Agriculture to be used in safeguarding the rights and welfare of human subjects used in research supported with USDA grant funds are contained in 45 CFR Part 46, and USDA regulations set forth in 7 CFR part 1c. All nonexempt research projects involving human subjects must be approved by an Institutional Review Board prior to commencing actual substantive work.

(C) **Animal Care** - The performing organization must comply with the Animal Welfare Act (7 U.S.C., 2131-2156); Public Law 89-544, 1996, and the regulations issued by the Department of Agriculture in 9 CFR parts 1, 2, 3, and 4. In the case of domesticated farm animals housed under farm conditions, the grantee must adhere to the principles stated in the Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching, Federation of Animal Sciences Societies, 1999. In the event a project involving the use of living vertebrate animals results in a grant award, funds will be released only after a qualified Institutional Animal Care and Use Committee has approved the project.

5.9 Grantee Commitments

Upon issuance of a research grant by USDA, the awardee will be required to make certain legal commitments through acceptance of the award document and the terms and conditions attached thereto, as well as any project-specific terms or conditions outlined. Most of these terms and conditions are contained in USDA's Uniform Federal Assistance Regulations, 7 CFR Part 3015, which will be incorporated into all Phase I awards resulting from this program solicitation and will be mailed in the package of materials when the research grant is forwarded to the awardee for acceptance. These regulations primarily consolidate internal policies and procedures relating to USDA's assistance programs and implement various Federally issued assistance policies, including applicable Federal cost principles and uniform administrative requirements. Advance copies of these regulations are available upon request.

5.10 Additional Information

(A) This program solicitation is intended for informational purposes and reflects current planning. If there is any inconsistency between the information contained herein and the terms of any resulting SBIR funding agreement, the terms of the funding agreement are controlling.

(B) Before the award of an SBIR funding agreement, USDA requires the submission of certain organizational management, personnel, and

financial information to assure responsibility of the proposer, including certification that the proposing organization is in compliance with the Civil Rights Act of 1964. Form CSREES-666 (both sides) should be completed to provide the necessary organizational information, and Form CSREES-665 should be used to certify compliance with Title VI of the Civil Rights Act of 1964. (If portions of the information requested on Form CSREES-666 are not applicable to the proposing organization or entity, "N/A" should be written in the space provided.) **These forms will be provided to the small business concern by the Office of Extramural Programs, CSREES, prior to the forwarding of the funding agreement for acceptance.** The information contained in both forms must normally be submitted **on a one-time basis only**. (If sufficient changes occur within the organization to warrant submission of new or additional information, additional forms should be requested by calling (202) 401-5050.) It is anticipated that all Phase I awardees will be required to submit the above information, but Phase II awardees will be concerned primarily with submitting new forms **only** if they have undergone significant changes in organization, personnel, finance, or policies including those relating to civil rights. **Phase II awardees will be asked to submit an updated statement of financial condition (such as the latest audit report, financial statement or balance sheet).**

(C) If a proposer or a grantee is contemplating any type of transaction involving the entity (i.e., merger, spin-off, or sale), it is advised that the proposer or the grantee contact the Director of the SBIR program for knowledge of how the transaction may affect a potential grant or the grant, as applicable.

(D) USDA is not responsible for any monies expended by the proposer prior to the award of any funding agreement.

(E) This program solicitation is not an offer by USDA and does not obligate USDA to make any specific number of awards. Also, awards under this program are contingent upon the availability of funds.

(F) **Unsolicited proposals will not be accepted** under the SBIR program in either Phase I or Phase II.

5.11 Certifications

(A) **Instructions for Statement as to Delinquency on Federal Debts by Applicants for Federal Assistance** - Pursuant to OMB Circular A-129, (implemented by USDA in 7 CFR Part 3), "Except where required by law or approved by the head of the agency, no award of Federal funds shall be made to an applicant who is delinquent on a Federal debt until the delinquent account is made current or satisfactory arrangements are made between affected agencies and the debtor." The certification of non-delinquency applies only to the organization requesting financial assistance and not to the individual project director. By indicating "no" for item 8, Form CSREES-667, Proposal Cover Sheet, the applicant is providing the statement of non-delinquency on any Federal debt. For the purposes of this statement, the following definitions of delinquency apply:

(1) Direct loans - a debt more than 31 days past due on a scheduled payment.

(2) Grants - recipients of a "Notice of Grants Cost Disallowance" who have not repaid the disallowed amount or who have not resolved the disallowance.

(3) Guaranteed and insured loans - recipients of a loan guaranteed by the Federal Government that the Federal Government has repurchased from a lender because the borrower breached the loan agreement and is in default.

Examples of debts include delinquent taxes, audit disallowances, guaranteed and direct student loans, housing loans, farm loans, business loans, Department of Education institutional loans, benefit overpayments and other miscellaneous administrative debts.

NOTE: An applicant answering "Yes" to this question on Form CSREES-667 must attach explanatory information detailing all relevant particulars concerning the Federal debt.

(B) **Certifications Regarding Drug-Free Workplace Requirements (Grants)** - These certifications are required by 7 CFR Part 3017, implementing the Drug-Free Workplace Act of 1988, 41 U.S.C. 701 et seq. Copies of the regulations may be obtained by contacting the Proposal Services Unit at (202) 401-5048, or via the Office of Extramural Programs

web page at the following address: www.reeusda.gov/crgam/oep.

Certification Regarding Drug-Free Workplace Requirements, Alternative I, For Grantees Other Than Individuals

The grantee certifies that it will or will continue to provide a drug-free workplace by:

(a) Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance is prohibited in the grantee's workplace and specifying the actions that will be taken against employees for violation of such prohibition;

(b) Establishing an ongoing drug-free awareness program to inform employees about --

(1) The dangers of drug abuse in the workplace;

(2) The grantee's policy of maintaining a drug-free workplace;

(3) Any available drug counseling, rehabilitation, and employee assistance programs; and

(4) The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace;

(c) Making it a requirement that each employee to be engaged in the performance of the grant be given a copy of the statement required by paragraph (a);

(d) Notifying the employee in the statement required by paragraph (a) that, as a condition of employment under the grant, the employee will --

(1) Abide by the terms of the statement; and

(2) Notify the employer in writing of his or her conviction for a violation of a criminal drug statute occurring in the workplace no later than five calendar days after such conviction;

(e) Notifying the agency in writing, within ten calendar days after receiving notice under subparagraph (d)(2) from an employee or otherwise receiving actual notice of such conviction. Employers of convicted employees must provide notice, including position title, to every grant officer on whose grant activity the convicted employee was working, unless the Federal agency has designated a central point for the receipt of such notices. Notice shall include the identification number(s) of each affected grant;

(f) Taking one of the following actions, within 30 calendar days of receiving notice under subparagraph (d)(2), with respect to any employee who is so convicted --

(1) Taking appropriate personnel action against such an employee, up to and including termination, consistent with the requirements of the Rehabilitation Act of 1973, as amended, 29 U.S.C. 701 et seq.; or

(2) Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;

(g) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (a), (b), (c), (d), (e) and (f).

Certification Regarding Drug-Free Workplace Requirements, Alternative II, For Grantees Who Are Individuals

(a) The grantee certifies that, as a condition of the grant, he or she will not engage in the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance in conducting any activity with the grant.

(b) If convicted of a criminal drug offense resulting from a violation occurring during the conduct of any grant activity, he or she will report the conviction, in writing, within 10 calendar days of the conviction, to the grant officer or other designee, unless the Federal agency designates a central point for the receipt of such notices. When notice is made to such a central point, it shall include the identification number(s) of each affected grant.

Instructions for Certification of Drug-Free Workplace Requirements

1. By signing Form CSREES-667, the grantee is providing the certification set forth above.

2. The certification is a material representation of fact upon which reliance is placed when the agency awards the grant. If it is later determined that the grantee knowingly rendered a false certification, or otherwise violates the requirements of the Drug-Free Workplace Act, the agency, in addition to any other remedies available to the Federal Government, may take action authorized under the Drug-Free Workplace Act.

3. Workplaces under grants, for grantees other than individuals, need not be identified on the certification. If known, they may be identified in the grant application. If the grantee does not identify the workplaces at the time of application, or upon award, if there is no application, the grantee must keep the identity of the workplace(s) on file in its office and make the information available for Federal inspection. Failure to identify all known workplaces constitutes a violation of the grantee's drug-free workplace requirements.

4. Workplace identifications must include the actual address of buildings (or parts of buildings) or other sites where work under the grant takes place. Categorical descriptions may be used (e.g., all vehicles of a mass transit authority or State highway department while in operation, State employees in each local unemployment office, performers in concert halls or radio studios).

5. If the workplace identified to the agency changes during the performance of the grant, the grantee shall inform the agency of the change(s), if it previously identified the workplaces in question (see paragraph three).

6. Definitions of terms in the Nonprocurement Suspension and Debarment common rule and Drug-Free Workplace common rule apply to this certification. Grantees' attention is called, in particular, to the following definitions from these rules:

Controlled substance means a controlled substance in Schedules I through V of the Controlled Substances Act (21 U.S.C. 812) and as further defined by regulation at 21 CFR 1308.11 through 1308.15;

Conviction means a finding of guilt (including a plea of nolo contendere) or imposition of sentence, or both, by any judicial body charged with the responsibility to determine violations of the Federal or State criminal drug statutes;

Criminal drug statute means a Federal or non-Federal criminal statute involving the manufacture, distribution, dispensing, use, or possession of any controlled substance;

Employee means the employee of a grantee directly engaged in the performance of work under a grant, including: (i) all "direct charge" employees; (ii) all "indirect charge" employees unless their impact or involvement is insignificant to the performance of the grant; and, (iii) temporary personnel and consultants who are directly engaged in the performance of work under the grant and who are on the grantee's payroll. This definition does not include workers not on the payroll of the grantee (e.g., volunteers, even if used to meet a matching requirement; consultants or independent contractors not on the grantee's payroll; or employees of subrecipients or subcontractors in covered workplaces).

(C) **Debarment or Suspension Requirements - Certification Regarding Debarment, Suspension, and Other Responsibility Matters - Primary Covered Transactions, and Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion - Lower Tier Covered Transactions (Form AD-1048).**

These certifications are required by the regulations implementing Executive Order 12549, Debarment and Suspension, 7 CFR 3017.510, Participants' responsibilities. Copies of the regulation may be obtained by contacting the Proposal Services Unit at (202) 401-5048, or via the Office of Extramural Programs web page at the following address: www.reeusda.gov/crgam/oep.

Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion - Lower Tier Covered Transactions (Form AD-1048)

Form AD-1048 containing certification for each lower tier covered transaction will be sent to each Phase I and Phase II grantee at the time of award with the award letter. It should not be submitted to CSREES but should be maintained by the

applicant with the other records relating to the award project.

Certification Regarding Debarment, Suspension, and Other Responsibility Matters - Primary Covered Transactions

(1) The prospective primary participant certifies to the best of its knowledge and belief, that it and its principals:

(a) Are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any Federal department or agency;

(b) have not within a three-year period preceding this proposal been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State or Local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;

(c) are not presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State or Local) with commission of any of the offenses enumerated in paragraph (1)(b) of this certification; and

(d) have not within a three-year period preceding this application/proposal had one or more public transactions (Federal, State or Local) terminated for cause or default.

(2) Where the prospective primary participant is unable to certify to any of the statements in this certification, such prospective participant shall attach an explanation to this proposal.

Instructions on Certification Regarding Debarment And Suspension

1. By signing Form CSREES-667, the prospective primary participant is providing the certification for primary covered transactions set forth above.

2. The inability of a person to provide the certification will not necessarily result in denial of participation in this covered transaction. The prospective participant shall submit an explanation of why it cannot provide the certification. The certification or explanation will be considered in connection with the department or agency's determination whether to enter into this transaction. However, failure of the prospective primary participant to furnish a certification or an explanation shall disqualify such person from participation in this transaction.

3. The certification in this clause is a material representation of fact upon which reliance was placed when the department or agency determined to enter into this transaction. If it is later determined that the prospective primary participant knowingly rendered an erroneous certification, in addition to other remedies available to the Federal Government, the department or agency may terminate this transaction for cause or default.

4. The prospective primary participant shall provide immediate written notice to the Authorized Departmental Officer in accordance with 7 CFR Part 3017.510(c) if at any time the prospective primary participant learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.

5. The terms "covered transaction," "debarred," "suspended," "ineligible," "lower tier covered transaction," "participant," "person," "primary covered transaction," "principal," "proposal," and "voluntarily excluded," as used in this clause, have the meaning set out in the Definitions and Coverage sections of the rules implementing Executive Order 12549. You may contact CSREES for assistance in obtaining a copy of those regulations.

6. The prospective primary participant agrees by certification that, should the proposed covered transaction be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is debarred, suspended, declared ineligible, or voluntarily excluded from participation in this covered transaction, unless authorized by the department or agency entering into this transaction.

7. The prospective primary participant further agrees by certification that it will include the clause titled "Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion - Lower Tier Covered Transactions," from Form AD-1048, provided by the department or agency entering into

this covered transaction, without modification, in all lower tier covered transactions and in all solicitations for lower tier covered transactions.

8. A participant in a covered transaction may rely upon a certification of a prospective participant in a lower tier covered transaction that is not debarred, suspended, ineligible, or voluntarily excluded from the covered transaction, unless it knows that the certification is erroneous. A participant will require its prospective lower tier participants to provide immediately written notice to the proposer if at any time the prospective lower tier participant learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances. A participant may decide the method and frequency by which it determines the eligibility of its principals. Each participant may, but is not required to, check the Nonprocurement List. As used herein, lower tier covered transactions generally include:

   a. Any transaction (other than a procurement contract) for goods and services, regardless of type;

   b. Any procurement contract for goods and services, regardless of type, that is expected to equal or exceed the Federal cap on small purchases (currently, $100,000); and

   c. Any procurement contract for goods and services, regardless of amount, under which the recipient will have a critical influence on or substantive control over the covered transaction (i.e., project director and providers of federally required audit services).

9. Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render in good faith the certification required by this clause. The knowledge and information of a participant is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

10. Except for transactions authorized under paragraph 6 of these instructions, if a participant in a covered transaction knowingly enters into a lower tier covered transaction with a person who is suspended, debarred, ineligible, or voluntarily excluded from participation in this transaction, in addition to other remedies available to the Federal Government, the department or agency may terminate this transaction for cause or default.

(D) **Notice to Applicants - Certification/Disclosure Requirements Related to Lobbying** - Section 319 of Public Law 101-121 (31 U.S.C. 1352), imposes prohibitions and requirements for disclosure and certification related to lobbying on recipients of Federal contracts, grants, cooperative agreements, and loans. Certain provisions of the law also apply to Federal commitments for loan guarantees and insurance; however, it provides exemptions for Indian tribes and tribal organizations.

Current and prospective recipients (and their subtier contractors and/or subgrantees) are prohibited from using Federal funds, other than profits from a Federal contract, for lobbying Congress or any Federal agency in connection with the award of a particular contract, grant, cooperative agreement or loan. In addition, for each award action in excess of $100,000 (or $150,000 for loans) on or after December 23, 1989, the law requires recipients and their subtier contractors and/or subgrantees to: (1) certify that they have neither used nor will use any appropriated funds for payment to lobbyists, (2) disclose the name, address, payment details, and purpose of any agreements with lobbyists whom recipients or their subtier contractors or subgrantees will pay with profits or **nonappropriated** funds on or after December 23, 1989; and (3) file quarterly updates about the use of lobbyists if material changes occur in their use. The law establishes civil penalties for noncompliance.

USDA, CSREES regulations implementing Section 319 of Public Law 101-121 are at 7 CFR Part 3018. Copies of 7 CFR Part 3018 may be obtained by contacting the Proposal Services Unit at (202) 401-5048, or via the Office of Extramural Programs web page at the following address: www.reeusda.gov/crgam/oep.

Certification Regarding Lobbying - Contracts, Grants, Loans, and Cooperative Agreements - In signing Form CSREES-667, the applicant certifies, to the best of his or her knowledge and belief, that:

1. No Federal appropriated funds have been paid or will be paid, by or on behalf of the applicant, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the

making of any Federal grant, the making of any Federal Loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan or cooperative agreement;

2. If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with a Federal contract, grant, loan, or cooperative agreement, the applicant shall complete and submit Standard Form-LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions;

3. The applicant shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

(E) **Compliance with the National Environmental Policy Act (NEPA)** - As outlined in 7 CFR Part 3407 (the CSREES regulations implementing NEPA), the environmental data or documentation for any proposed project is to be provided to CSREES in order to assist CSREES in carrying out its responsibilities under NEPA. In some cases, however, the preparation of environmental data may not be required. Certain categories of actions are excluded from the requirements of NEPA.

In order for CSREES to determine whether any further action is needed with respect to NEPA (e.g., preparation of an environmental assessment (EA) or environmental impact statement (EIS)), pertinent information regarding the possible environmental impacts of a proposed project is necessary; therefore, the National Environmental Policy Act Exclusions Form (Form CSREES-2006) provided must be included in the proposal indicating whether the applicant is of the opinion that the project falls within one or more of the categorical exclusions. Form CSREES-2006 should be included at the end of the proposal.

Even though a project may fall within the categorical exclusions, CSREES may determine that an EA or an EIS is necessary for an activity, if substantial controversy on environmental grounds exists or if other extraordinary conditions or circumstances are present which may cause such activity to have a significant environmental effect.

6.0 SUBMISSION OF PROPOSALS

6.1 When to Submit

All Phase I proposals must be RECEIVED at USDA by close of business (COB) on August 30, 2002 (5:00 p.m. Eastern Time). Proposals received after this deadline will not be considered for funding.

All Phase II proposals must be received at USDA by COB on February 6, 2003. Proposals received after this deadline will not be considered for funding.

Only those small businesses previously receiving Phase I awards in either fiscal years 2001 or 2002 are eligible to submit Phase II proposals in fiscal year 2003. The SBIR Program Director will send a letter to all eligible Phase I awardees requesting Phase II proposals.

For the convenience of all potential proposers, the following schedule is provided for informational purposes:

Phase I	
Deadline date	August 30, 2002
Period of research performance	May 15, 2003 - November 30, 2003
Final report due at USDA	December 31, 2003

Phase II	
Deadline date	February 6, 2003
Beginning period of research performance approximately	September 1, 2003

6.2 What to Submit

Proposers under both Phase I and Phase II are requested to submit an **original and 15 copies** of all proposals. These proposals must contain all of the information, **arranged in the same order,** as that outlined in section 3.0.

6.3 Where to Submit

Applicants are strongly encouraged to submit proposals via overnight mail or delivery service to ensure timely receipt by USDA. The address for hand-delivered proposals or proposals submitted using an express mail or overnight courier service is:

SBIR Program
c/o Proposal Services Unit
Cooperative State Research, Education, and Extension Service
U.S. Department of Agriculture
Room 1420, Waterfront Centre
800 9th Street, S.W.
Washington, D.C. 20024
Telephone: (202) 401-5048

Proposals sent via the U.S. Postal Service must be sent to the following address:

SBIR Program
c/o Proposal Services Unit
Cooperative State Research, Education, and Extension Service
U.S. Department of Agriculture
STOP 2245
1400 Independence Avenue, SW
Washington, D.C. 20250-2245

6.4 Acknowledgment of Proposals

The receipt of proposals will be acknowledged by e-mail. Therefore, applicants are encouraged to provide e-mail addresses, where designated, on the Proposal Cover Sheet, Form CSREES-667. If the applicant's e-mail address is not indicated, CSREES will acknowledge receipt of the proposal by letter. If the applicant does not receive an acknowledgment within 60 days of the submission deadline, please contact the Program Director (see subsection 1.1 for address, telephone, and facsimile numbers).

6.5 Bindings

Do not use special bindings or covers on proposals submitted in response to this program solicitation. Staple all pages together securely in the upper left-hand corner of each copy of each proposal.

6.6 Packaging

If possible, the original and all copies of each proposal should be mailed in one package. Due to the volume of proposals received, applications submitted in several packages are very difficult to identify and track. If it becomes necessary to mail copies of a proposal in more than one package, the number of packages should be marked on the outside of each. It is important that **all packages be mailed at the same time.**

6.7 Questions Pertaining to the USDA SBIR Program or to this Solicitation

Written or verbal questions of a general nature about the USDA SBIR program, as well as general questions pertaining to this solicitation (but **not** pertaining to requests for additional copies of the solicitation), should be directed to Dr. Charles F. Cleland, Director, SBIR Program (see subsection 1.1 for address, telephone, and facsimile numbers).

6.8 Requests for Additional Copies of this Solicitation

Please note that this Program Solicitation is available through the USDA CSREES web page, www.reeusda.gov/sbir. CSREES encourages the use of the electronic document. However, if necessary, paper copies of this solicitation may be ordered by writing to the U.S. Postal Service address shown in subsection 6.3 or by calling (202) 401-5048.

These materials may also be requested via Internet by sending a message with your name, mailing address (not e-mail) and phone number to psb@reeusda.gov which states that you want a copy of the application materials for the Fiscal Year 2003 Small Business Innovation Research Grants Program. The materials will then be mailed to you (not e-mailed) as quickly as possible.

6.9 Information on Proposal Status

It is anticipated that the evaluation of **Phase I** proposals will require approximately 6 months from August 30, 2002, and no information on proposal status will be available until final selections have been made. Both successful and unsuccessful proposers will be notified of final award decisions within approximately 6 months.

Evaluation of **Phase II** proposals will require approximately four months from February 6, 2003. Again, proposers are discouraged from making inquiries regarding the status of their proposals. All proposing organizations will be notified of final award decisions within approximately 4 months.

7.0 SCIENTIFIC AND TECHNICAL INFORMATION SOURCES

Listed below are some of the sources that can provide technology search and document services which may be useful in preparing SBIR proposals. They can be contacted directly for service and cost information.

National Agricultural Library
Service Desk
U.S. Department of Agriculture
10301 Baltimore Avenue
Beltsville, Maryland 20705-2351
(301) 504-5755

National Technology Transfer Center
Wheeling Jesuit University
316 Washington Avenue
Wheeling, West Virginia 26003
(304) 243-2455 or (800) 678-6882

National Technical Information Service
5285 Port Royal Road
Springfield, Virginia 22161
(800) 553-6847

Center for Technology Commercialization
1400 Computer Drive
Westborough, Massachusetts 01581-5043
(508) 870-0042

Great Lakes Industrial Technology Center
25000 Great Northern Corporate Center, Suite 260
Cleveland, Ohio 44070
(440) 734-0094

Mid-Atlantic Technology Applications Center
University of Pittsburgh
3400 Forbes Avenue, Eureka Bldg., 5th Floor
Pittsburgh, Pennsylvania 15260
(412) 383-2500

Mid Continent Technology Transfer Center
Texas Engineering Extension Service
The Texas A&M University System
College Station, Texas 77840
(979) 845-8762

NERAC, Inc.
One Technology Drive
Tolland, Connecticut 06084-3900
(860) 872-7000

Rural Enterprises, Inc.
2912 Enterprise Blvd.
Durant, Oklahoma 74702
(580) 924-5094

Sciencewise
300 Professional Drive, Suite 200
Gaithersburg, Maryland 20879
(301) 975-0103

Southern Technology Applications Center
College of Engineering
University of Florida
1900 SW 34th Street
Gainesville, Florida 32608
(352) 294-7822

8.0 RESEARCH TOPIC DESCRIPTIONS

SBIR proposals are solicited from the full range of topic areas that follow. Specific subtopics are listed only as **examples** of advanced applications or basic research of interest to USDA and are **not to be interpreted as exclusive.** It is USDA's intention to provide sufficient flexibility to obtain the greatest degree of creativity and innovation possible, consistent with overall SBIR and USDA program objectives. USDA reserves the right to shift proposals to a more appropriate topic when necessary for adequate review.

Proposals are encouraged that focus on problems dealing with bioterrorism and homeland security, especially as these issues relate to rural communities.

8.1 Forests and Related Resources

(A) Scope of Research

The objective of this topic is to develop environmentally sound techniques to increase productivity of forest land and to increase the utilization of materials and resources from forest lands. These areas deal with (1) increasing growth and yield through improving planting stock, reducing pathogens and insects, improving the soil or reducing harvesting impacts, and developing means to ensure survival of newly planted trees; (2) increasing the utility of the material grown in the forest through improving lumber yield from trees, utilizing greater percentages of trees, and using residues from forest and wood manufacturing systems; (3) reducing ecological damage from forest operations; (4) reducing the risk of and controlling wildfire on forest land; and (5) developing new products or technologies to increase the use of wood.

(B) Suggested Subtopics

Appropriate subtopics for innovative research proposals from small business concerns include, but are not limited to, the following:

(1) **Growth and yield**

- Improving growing stock, tissue culture, genetic manipulation or vegetative reproduction of forest trees and other means of increasing the regenerative abilities of forests.

- Reducing pathogens and insects - The volume of material lost to disease and insects exceeds that used for lumber and associated wood products. Subjects applicable here are those that reduce the impact of destructive agents.

- Improving soil or reducing harvesting impacts - The fixing of nitrogen by symbiotic agents through genetic manipulation or by mycorrhizae to increase forest productivity through nitrogen enrichment of forest soils; research to reduce soil erosion, compaction, or other alterations caused by harvesting or forest operations (that is, physical improvement of forest soils).

- Developing systems to increase the survival of newly planted trees through mechanical, physical, or chemical means that are environmentally safe.

(2) **Increasing the utility of forest-grown material**

- Improving lumber yield or other means of increasing the volume and worth of wood from individual trees.

- Utilizing a greater percentage of the tree through improved or new techniques of veneering or comminution so that new or improved reconstituted products can be made.

(3) **Reducing ecological damage by forest operations** - Research which provides for the economic recovery of resources from forests while raising potential productivity and reducing impacts to the ecological structure of the area of operation.

(4) **Developing technology that facilitates the control of wildfires on forest lands** - systems for detecting and managing wildfires; systems for reducing fuel loads in forests; tools and equipment for improving the efficacy and safety of fire fighters on the ground and in the air; communication and navigation systems for improving the coordination of fire management activities.

(5) **Developing new products or technologies to increase the use of wood** - Products using wood as a basic component of systems to replace or compete with construction materials or techniques.

8.2 Plant Production and Protection

Proposals submitted to this topic area will be divided between two review panels, one dealing with biological approaches, and the other dealing with engineering approaches.

Biological Approaches

(A) Scope of Research

The objective of this topic is to examine means of enhancing crop production by reducing the impact of harmful agents, enhancing the impact of new methods of plant manipulation, and developing new crop plants and new uses for existing crops.

(B) **Suggested Subtopics**
Examples of research activities that would be appropriate for small business concerns include, but are not limited to, the following:

(1) **Plant improvement** - Improving the efficiency of crop production by utilizing innovative methods such as those of biotechnology, molecular biology, genomics, tissue culture, and embryogenesis to produce crops with improved quality, yield and agronomic or horticultural traits.

(2) **New crops** - Developing new crop plants (both terrestrial and aquatic) as sources of food, fiber or industrial products.

(3) **Plant protection** - Reducing the impact of plant pathogens, insect pests, and abiotic stress on crop plants; increasing plant resistance to plant pathogens, insect pests, and abiotic stress.

Engineering Approaches

(A) **Scope of Research**
The objective of this topic is to examine means of enhancing crop production by reducing the impact of harmful agents and developing effective crop production systems that are economically and environmentally sound.

(B) **Suggested Subtopics**
Examples of research activities that would be appropriate for small business concerns include, but are not limited to, the following:

(1) **Improved crop production methods or strategies** - Enhancing the efficiency of crop production by utilizing innovative methods and equipment for planting, growing and harvesting crop plants, including optimization of inputs and reduction of environmental impacts by implementing the use of precision farming technology, sensors, information technology, and remote sensing.

(2) **Plant protection** - Reducing the impact of plant pathogens, insect pests and competing vegetation on crop plants by developing efficient and environmentally safe pesticide and herbicide usage equipment.

(3) **Energy conservation** - Developing crop management systems, farm and greenhouse structures, and waste utilization strategies for efficient use of energy.

8.3 Animal Production and Protection

(A) **Scope of Research**
The overall objective of this topic area is to develop knowledge that will enable producers of food animals to increase production efficiency and to assure a reliable, safe supply of animal protein and other animal products while conserving resources and reducing costs of production. Some examples of the areas of research to be supported are: clarification of the nutritional requirements of food animals for improved growth and feed efficiency; determination of hormonal and cellular mechanisms which control reproduction and multiple births; clarification of genetic processes that result in food animals with superior characteristics; improved methods of disposal of animal wastes; and diagnosis, treatment and control of food animal diseases, parasitisms and other animal health hazards.

(B) **Suggested Subtopics**

Appropriate subtopics for innovative research proposals from small business concerns include, but are not limited to, the following:

(1) **Animal Production**

(a) **Animal nutrition and digestive physiology** - Research directed at understanding the interrelationships between alimentary microbial ecosystems, digestive processes, and the host animal, and providing nutritional characterization of feedstuffs and integrated nutrient management to enhance production efficiency.

(b) **Animal reproduction** - Research on the control of estrus, ovulation and fertilization; enhanced embryo survival and development; enhanced parturition and perinatal survival; and advances in embryo technology such as sex control, twinning, frozen embryos and cloning.

(c) **Animal genetics and breeding** - Studies aimed at germplasm improvement in food animals that will provide animals with

superior characteristics in areas such as reproduction, growth and development, lactation and egg production, lean-to-fat ratios, and disease resistance. These studies may employ innovative application of traditional methods, or incorporate novel biotechnological approaches, including, but not limited to cell and tissue culture, molecular biology, and genomics.

(d) **Livestock management systems** - Development of systems or processes that can be applied to food animal production enterprises that will provide greater efficiency in the production process and reduce the impact of these operations on the environment.

(2) **Animal Protection**

(a) **Diagnostic tests** - Development of diagnostic tests for specific diseases and agricultural chemicals which pose a health hazard to food animals and a residue problem in animal food products.

(b) **Therapeutic methods** - Treatment or treatment methods for acute or chronic health problems of food animals caused by specific infectious or non-infectious agents, parasitisms, chemicals and toxic agents, poisonous plants, injuries and other animal health hazards.

(c) **Immunization methods** - Vaccines, bacterins or other methods to establish or enhance resistance of food animals to infectious diseases and parasitisms.

(d) **Pest control strategies** - Development of alternative pest control or eradication methods so as to limit the use of and dependence on biotoxic substances. Such alternatives may include biological methods, sterile male techniques, artificial pheromones, and similar strategies.

(e) **Preventive management** - Development of management methods designed to protect food animals against health hazards.

(f) **Animal health costs** - Development of methodologies to accurately assess economic losses to animal health hazards and to measure economic benefits of alternative methods of prevention and control.

8.4 Air, Water, and Soils

(A) **Scope of Research**

The objective of this research area is to develop technologies for conserving and protecting air, water, and soil resources while sustaining optimal farm and forest productivity and the manufacture of resulting agricultural commodities.

(B) **Suggested Subtopics**

Examples of appropriate subtopics for research proposals from small businesses include, but are not limited to, the following:

(1) **Air Resources** - Development of innovative, energy-efficient, cost-effective products, processes, or services that optimize: **reduced soil erosion** by wind; monitoring **air quality; abatement of air pollution** stemming from agricultural and forestry enterprises; **wind utilization** for agricultural purposes.

(2) **Water Resources** - Development of innovative, energy-efficient, cost effective products, processes, or services that optimize: **water conservation**, monitoring, restoration and maintenance of **water quality**, and proper **irrigation** usage to meet current and future agricultural and forestry needs.

(3) **Soil Resources** - Development of innovative, energy-efficient, cost-effective products, processes, or services that minimize the **loss of soil and soil nutrients** or **alteration of the physical and chemical nature of soil**; and technologies that **enhance soil properties** while **restricting environmental perturbation**.

8.5 Food Science and Nutrition

(A) **Scope of Research**

The objectives of food science and nutrition research programs are to develop new knowledge and a better understanding of the characteristics of the foods we eat and their nutritional impact; to

apply new knowledge to improve our foods and our diets; and to systematically apply new knowledge to the production of useful new food products, processes, materials and systems, including application of nutritional information to consumer foods and food service systems.

(B) Suggested Subtopics

Research opportunities are many and varied. Areas appropriate for innovative research proposals from small business concerns might include, but not necessarily be limited to, the following:

(1) **Chemistry and biochemistry** - Novel or rapid assay or bioassay techniques for food constituents, nutrients, properties, or interactions. Quality control techniques or rapid methods for in-plant nutrient analyses are needed.

(2) **Microbiology and toxicology** - Rapid, efficient methods for determining presence of organisms and detecting the development of toxic metabolites, including systems for determining shelf-life and "pull date" of food items, are needed.

(3) **Processing** - Methods for automation of processes and tests; rapid analyses and cataloging of physical properties; processing parameters; package design; design of material, energy- and water-efficient processes for small industries; development of specialty products or processes; on-line monitoring and control of nutrient, ingredient, or additive levels.

(4) **Economics and statistics** - Improved sampling procedures for dry mixes; cost/benefit analyses; and modeling systems, including distribution, warehousing and retailing systems.

(5) **Nutrition Education** - Developing and using information technology to convey important nutritional information and awareness to the public.

8.6 Rural and Community Development

(A) Scope of Research

The objectives of this research area are to foster, promote, or improve the well-being of rural Americans. This program supports research that will result in commercial products or services that are focused on issues and problems related to the economic development and social enhancement of rural areas, small towns, rural people, rural organizations, and rural institutions. Proposals submitted to this area should not concentrate primarily on the development of new technology, but rather on applying new or existing technology to address important issues and/or solving significant problems of importance to rural America. Proposals that involve development of new technology should explicitly discuss the specific rural problem or opportunity that will be examined, and how this technology will successfully address the problem or opportunity. The proposals do not need to be centered on agriculture, per se, but may be focused on any area (e.g., information systems, education, health care) that has the potential of providing significant benefits to rural Americans. Most of the competitive proposals submitted to this topic should include a market feasibility study as one of the research objectives.

(B) Suggested subtopics

Examples of appropriate subtopics for research proposals from small businesses include, but are not limited to, the following:

(1) **Income or Employment Opportunities** - Efforts are needed that will foster or promote the development of new and improved income or employment opportunities for people in rural areas. Topics in this area may include products or services that enhance availability and capabilities of entrepreneurs, promote innovative ways to organize production systems to increase efficiencies and profitability of rural firms, stimulate the development of new agricultural enterprises to improve farm profitability, and development of new technologies that will promote job creation and income growth in both the farm and non-farm sector of the rural economy.

(2) **Service Delivery by Local Governments and Public Institutions** - Approaches are encouraged that will result in improvements in the service delivery capabilities of local governments and public institutions. Areas of interest include educational programs that address the specific needs of people in rural

areas, new housing designs that enhance the availability, quality and affordability of rural housing, improved health care delivery systems for different segments of the rural population, information and managerial systems that improve the efficiency and effectiveness of local governments, and improvements in critical areas such as transportation, telecommunications, waste disposal and resource management.

(3) **Sustainable and Resilient Communities** - Procedures are needed that will help rural communities to become more sustainable and resilient when faced with unexpected natural or terrorist-caused disasters. Communities need to develop plans for dealing with disruptions in critical services, to strengthen emergency preparedness capability, to improve the telecommunications and information technology infrastructure, to educate members of the community on steps to take in case of a disaster, and to identify critical facilities that could be utilized in the event of an emergency.

8.7 Aquaculture

(A) Scope of Research

The objective of this research area is to enhance the knowledge and technology base necessary for the continued growth of the domestic aquaculture industry as a form of production agriculture. Emphasis is placed on research leading to improved production efficiency and increased competitiveness of private sector aquaculture in the United States. Studies on commercially important (or potentially important) species of fish, shellfish and plants, from both freshwater and marine environments, can be addressed.

(B) Suggested Subtopics

Examples of appropriate subtopics for research proposals from small businesses include, but are not limited to the following:

(1) **Reproductive Efficiency** - Novel or innovative approaches to improve reproductive efficiency in aquaculture including: greater control of maturation, ovulation, and fertilization; improved gamete and embryo storage; improved larval rearing techniques; enhanced reproductive performance of broodstock; and methods to control sex determination.

(2) **Genetic Improvement** - Novel or innovative approaches to improve production efficiency through genetic improvement of aquacultural stocks including: genetic mechanisms of sex determination; genetic basis for inheritance of commercially important traits such as growth, cold tolerance and pathogen susceptibility; identification of major genes affecting performance; application of molecular biology and genomics and the integration of this technology into breeding programs; basic gene structure and expression in aquatic species; performance evaluation of aquacultural stocks and utilization of crossbreeding and hybridization.

(3) **Integrated Aquatic Animal Health Management** - Novel or innovative approaches to reducing acute and chronic losses related to aquatic animal health in aquaculture production systems through an integrated holistic approach including: physiological stress related to the quality of the aquatic production system; genetic, environmental and nutritional components of aquatic health management; control of predation in aquaculture production systems; development of new vaccines or immunization procedures to enhance resistance to infectious diseases and parasitisms; development of diagnostic tests for specific diseases that pose a health hazard; and development of improved treatment methods for acute or chronic health problems caused by specific infectious or non-infectious agents, parasitisms, injuries, and chemical and toxic agents.

(4) **Improved Production Systems and Management Strategies** - Novel or innovative approaches to improving existing or alternative production system design and management strategies including: development of biological, engineering and economic design criteria and models; enhancement of water quality in existing production systems through aeration, flow patterns, etc.; characterization, handling and treatment of effluent from aquacultural production systems; improved harvesting methods and strategies.

8.8 Industrial Applications

(A) **Scope of Research**

The objective of this research area is to develop new or improved technologies that will lead to **increased production of industrial products from agricultural materials.** This research will lead to new opportunities to diversify agriculture and enhance agriculture's role as a reliable supplier of raw materials to industry. Appropriate research areas are: development of new crops that have the potential of producing raw materials that can be converted into useful industrial products; development of procedures for enhanced recovery of critical raw materials from agricultural commodities; development of improved technology for converting agriculturally derived raw materials into useful industrial products; and development of industrial products derived from agricultural materials to make them more effective and/or more cost competitive with non-agriculturally derived industrial products.

(B) **Suggested Subtopics**

Examples of appropriate subtopics for research proposals from small businesses include, but are not limited to, the following:

(1) **Oils and Lubricants** - Development of new agricultural sources of industrial oils and waxes for use as lubricants, cosmetics, soaps and detergents, plastics, paints, and many types of coatings.

(2) **Natural Rubber** - Improved technology for the production of resin and improvement in the quality of the natural rubber, and research into new applications for bagasse and other co-products.

(3) **Fuels** - New and improved technology for conversion of agriculturally important biomass material into alcohol and other products to be used as fuel additives and fuel substitutes.

(4) **Chemicals from Starch** - Development of new products such as absorbants and specialty chemicals from corn and other starchy crops.

(5) **Fibers** - New and improved technology for production of fiber from kenaf and other promising new fiber crops.

8.9 Marketing and Trade

(A) **Scope of Research**

The objective of this research area is to identify an array of innovative marketing strategies to increase sales of agricultural, forestry, and aquacultural products (raw commodities, plus processed, value-added food, feed, and industrial products derived from these commodities), both domestically and abroad. This research will assess and evaluate the type, size, and location of market opportunities for specific U.S. products or categories of products; develop specific strategies to gain entry into these markets or expand sales in current markets for specific products or categories of products; identify barriers to trade and develop specific strategies that neutralize these barriers; develop advanced information systems that provide more complete, relevant and timely information relative to temporal marketing opportunities; and develop integrated management systems that would permit maximum efficiencies in assembling, handling, processing, packaging, transporting, and shipping products. Where appropriate, foreign travel may be approved provided justification is adequately documented in the proposal.

(B) **Suggested Subtopics**

Examples of appropriate subtopics for research proposals from small businesses include, but are not limited to, the following:

(1) **Development of Marketing Systems** - Develop post harvest, integrated management systems that take raw, partially processed, or fully processed products and improves the efficiency in assembling, packing, processing, and shipping products to "niche," regional, national, and international markets. Included in this subtopic would be the development of methods that define strategies to: (a) better integrate collection/assembly systems, (b) minimize seasonal variations in production and processing levels; (c) improve product characteristics through the use of such systems; and, (d) design more efficient packaging, storing, and transportation systems, including intermodal systems.

(2) **Development of Innovative Real-Time/Near Real-Time Information Systems** - Develop current and projected economic information on product sales, potential demand, prices, quality

standards and specifications, varietal and packaging preferences, and relevant time periods in either real-time, or near-real-time to enable firms to respond more rapidly to national and international marketing opportunities. Also involved in this subtopic would be innovative information products that can inform businesses of the availability, features, and economics of new technologies and innovations, preferably using electronic media with interactive features.

(3) **Assessments and specification of marketing opportunities -** Identify new national and international markets, or the potential for increasing sales of U.S. forestry, agricultural, and aquacultural products in these markets. Quantify to the extent possible, market characteristics determining demand, product demand, and market structure; other changes relative to consumption patterns at home and abroad; shifts in retail and wholesale marketing; shifts in food manufacturing; and other changes that are relevant to successful marketing.

8.10 Wildlife

(A) Scope of Research

The objective of this research area is to develop new or improved technologies and environmentally sound approaches for improved management of wildlife that will reduce the adverse impact of wildlife on agriculture and people and enhance the sustainability of wildlife populations. This program will focus on wildlife in terrestrial (including birds), freshwater and estuarine environments, but not the marine environment. This will include both the influence of wildlife on agriculture and the influence of agriculture on wildlife.

(B) Suggested Subtopics

Examples of appropriate subtopics for research proposals from small businesses include, but are not limited to, the following:

(1) **Wildlife Control** - Improved control methods for mitigating the influence of animals on crop plants, ornamental plants, livestock and aquaculture species are needed. Emphasis should be placed on development of non-lethal approaches to address wildlife control problems.

(2) **Wildlife Management** - Development of methods and approaches for improved management of wildlife populations are needed. The emphasis should be on maintaining the sustainability of wildlife populations or improving the survivability of endangered species.

(3) **Wildlife Reproduction and Health** - Improved methods for controlling wildlife populations in order to maintain them at sustainable levels are needed. Research is also needed on vaccine development and other approaches for controlling the spread of diseases within wildlife populations or from wildlife to agricultural animals and people.

(4) **Habitat Management** - Improved methods of habitat management that will enhance the sustainability of wildlife populations and reduce their impact on agriculture, human health and property are needed. These methods may include approaches to maintain healthy ecosystems as well as approaches for ecosystem restoration where this will have a beneficial impact on important wildlife species.

UNITED STATES DEPARTMENT OF AGRICULTURE

SMALL BUSINESS INNOVATION RESEARCH

SOLICITATION NO. USDA / 03-1

OMB Approved 0524-0025

PHASE I AND PHASE II

PROPOSAL COVER SHEET

Proposal No. (for USDA use only)
Date Received

SUBMITTED	Firm:
	Mailing Address:

Project Title:

Topic No. and Area (check appropriate box; see Section 8.0)

- ☐ 8.1 Forests and Related Resources
- ☐ 8.2 Plant Production and Protection
- ☐ 8.3 Animal Production and Protection
- ☐ 8.4 Air, Water and Soils
- ☐ 8.5 Food Science and Nutrition
- ☐ 8.6 Rural and Community Development
- ☐ 8.7 Aquaculture
- ☐ 8.8 Industrial Applications
- ☐ 8.9 Marketing and Trade
- ☐ 8.10 Wildlife

Amount Requested: ($)	**Proposed Duration (Mos.):**	**Congressional District No.:**	**YES**	**NO**

1. The above concern certifies that it meets the first two criteria of a small business concern as stated in this solicitation or that it will meet that definition at time of award. (See subsection 2.2).		
2. The above concern certifies that it qualifies as a socially and economically disadvantaged small business as defined in this solicitation (See subsection 2.4). (For statistical purposes only).		
3. The above concern certifies that it qualifies as a women-owned small business as defined in this solicitation (See subsection 2.5). (For statistical purposes only).		
4. The above concern certifies that the Project Director's primary employment (at least 51%) will be with proposing firm at the time of any resulting award and during the conduct of the proposed research (See subsection 2.2©)).		
5. The above concern certifies a minimum of two-thirds of the research (phase I) or one-half the research (phase II) will be performed by this firm (See subsection 2.2(D)).		
6. Will you permit the Government to disclose the title and technical abstract page of your proposed project, plus the name, address, and telephone number of the corporate official of your firm, if your proposal does not result in an award, to entities that may be interested in contacting you for future information?		
7. Do you plan to send, or have you sent, this proposal or a similar one to any other Federal agency? If yes, give acronym(s); e.g., DOE, NIH, NSF, etc.		
8. Is the organization delinquent on any Federal Debt? (See subsection 5.11). (If yes, attach explanatory information).		
9. Will the work in this proposal involve recombinant DNA, living vertebrate animals, or human subjects? (If yes, complete Form CSREES-2008).		
10. Is this proposal a resubmission of a proposal submitted earlier to the USDA SBIR Program (See subsection 3.3(D)). If yes, list the proposal number _____.		

By signing and submitting this proposal, the prospective grantee is providing the required certifications set forth in 7 CFR Part 3017, as amended, regarding Debarment and Suspension and Drug-Free Workplace; and 7 CFR Part 3018 regarding Lobbying. (Please read the Certifications and Instructions included in this solicitation before signing this form.) In addition, the prospective grantee certifies that the information contained herein is true and complete to the best of its knowledge and accepts as to any grant award, the obligation to comply with the terms and conditions of the Cooperative State Research, Education, and Extension Service in effect at the time of the award. *Submission of the Social Security Number is voluntary and will not affect the organization's eligibility for an award. However, it is an integral part of the CSREES information system and will assist in the processing of the proposal.

PROJECT DIRECTOR		**AUTHORIZED ORGANIZATIONAL OFFICIAL**	
Name and Title		Name and Title	
Address		Address	
Social Security Number	E-mail	E-Mail	
Telephone No.	Fax No.	Telephone No.	Fax No.
Signature	Date	Signature	Date

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0524-0025. The time required to complete this information collection is estimated to average 1.4 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

PROPRIETARY NOTICE (IF APPLICABLE, SEE SUBSECTION 5.4)

The following pages (specify) contain proprietary information which (name of proposing organization) requests not be released to persons outside the Government, except for purposes of evaluation.

U.S. DEPARTMENT OF AGRICULTURE

SMALL BUSINESS INNOVATION RESEARCH

OMB Approved 0524-0025

PHASE I AND PHASE II

PROJECT SUMMARY*

FOR USDA USE ONLY			
Program Office:	Solicitation No.:	Proposal No.:	Topic No.:

TO BE COMPLETED BY PROPOSER

Name and Address of Firm:	Name and Title of Project Director(s):

Title of Project (140-character maximum):

Technical Abstract (200-word limit):

Anticipated Results/Potential Commercial Applications of Research (100-word limit):

Keywords to Identify Technology/Research Thrust/Commercial Application (8-word maximum)

- The Project Summary must be suitable for publication by USDA in the event of an award. Do not include proprietary information on this page.

UNITED STATES DEPARTMENT OF AGRICULTURE
COOPERATIVE STATE RESEARCH, EDUCATION, AND EXTENSION SERVICE

OMB Approved 0524-0039
Expires 03/31/2004

BUDGET

ORGANIZATION AND ADDRESS				USDA AWARD NO.			
				DURATION PROPOSED MONTHS:____	DURATION PROPOSED MONTHS: ____	Non-Federal Proposed Cost-Sharing/Matching Funds (If required)	Non-federal Cost-Sharing/Matching Funds Approved by CSREES (If Different)
PROJECT DIRECTOR(S)				**Funds Requested by Proposer**	**Funds Approved by CSREES** (If different)		
A. Salaries and Wages	**CSREES-FUNDED WORK MONTHS**						
1. No. Of Senior Personnel	Calendar	Academic	Summer				
a. ____ (Co)-PD(s)				$	$	$	$
b. ____ Senior Associates							
2. No. of Other Personnel (Non-Faculty) a. _____ Research Associates/Postdoctorates							
b. ____ Other Professionals							
c. ____ Paraprofessionals							
d. ____ Graduate Students							
e. ____ Prebaccalaureate Students							
f. ____ Secretarial-Clerical							
g. ____ Technical, Shop and Other							
Total Salaries and Wages –							
B. Fringe Benefits (If charged as Direct Costs)							
C. Total Salaries, Wages, and Fringe Benefits (A plus B) –							
D. Nonexpendable Equipment (Attach supporting data. List items and dollar amounts for each item.)							
E. Materials and Supplies							
F. Travel							
G. Publication Costs/Page Charges							
H. Computer (ADPE) Costs							
I. All Other Direct Costs (In budget narrative, list items and dollar amounts, and provide supporting data for each item.)							
J. Total Direct Costs (C through I) –							
K. F&A/Indirect Costs (If applicable, specify rate(s) and base(s) for on/off campus activity. Where both are involved, identify itemized costs included in on/off campus bases.)							
L. Total Direct and F&A/Indirect Costs (J plus K) –							
M. Other –							
N. Total Amount of This Request –				$	$	$	$

O. Carryover – (If Applicable) ..... **Federal Funds: $** **Non-Federal funds: $** **Total $**

P. Cost-Sharing/Matching (Breakdown of total amounts shown on line N)		
Cash (both Applicant and Third Party) –	$	$
Non-Cash Contributions (both Applicant and Third Party) –	$	$

NAME AND TITLE (Type or print)	**SIGNATURE** (required for revised budget only)	**DATE**
Project Director		
Authorized Organizational Representative		
Signature (for optional use)		

UNITED STATES DEPARTMENT OF AGRICULTURE
COOPERATIVE STATE RESEARCH, EDUCATION, AND EXTENSION SERVICE

OMB Approval 0524-0039
Expires 03/31/2004

ASSURANCE STATEMENT(S) - FOR RESEARCH PROJECTS

STATEMENT OF POLICY - Institutions receiving CSREES funding for research are responsible for protecting human subjects, providing humane treatment of animals, and monitoring use of recombinant DNA. To provide for the adequate discharge of this responsibility, CSREES policy requires an assurance by the institution's Authorized Organizational Representative (AOR) that appropriate committees in each institution have carried out the initial reviews of protocol and will conduct continuing reviews of supported projects. CSREES also requires AOR certification by citing a timely date that an appropriate committee issued an approval or exemption.

NOTE: Check appropriate statements, supplying additional information when necessary.

1. INSTITUTION	2. CSREES PROJECT NUMBER OR AWARD NUMBER (if known)
	3. PROJECT DIRECTOR(S)

4. TITLE OF PROJECT

A. BIOSAFETY OF RECOMBINANT DNA

- ☐ Project does not involve recombinant DNA.
- ☐ Project involves recombinant DNA and was either approved ( ) or determined to be exempt ( ) from the NIH Guidelines by an Institutional Biosafety Committee (IBC) on _____ (Date).

This performing organization agrees to assume primary responsibility for complying with both the intent and procedures of the National Institutes of Health (NIH), DHHS Guidelines for Research Involving Recombinant DNA Molecules, as revised.

B. CARE AND USE OF ANIMALS

- ☐ Project does not involve vertebrate animals.
- ☐ Project involves vertebrate animals and was approved by the Institutional Animal Care and Use Committee (IACUC) on _____ (Date).

This performing organization agrees to assume primary responsibility for complying with the Animal Welfare Act (7 USC, 2131-2156), Public Law 89-544, 1996, as amended, and the regulations promulgated thereunder by the Secretary of Agriculture in 9 CFR Parts 1, 2, 3, and 4. In the case of domesticated farm animals housed under farm conditions, the institution shall adhere to the principles stated in the Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching, Federation of Animal Science Societies, 1999.

C. PROTECTION OF HUMAN SUBJECTS

- ☐ Project does not involve human subjects.
- ☐ Project involves human subjects and
  - ☐ Was approved by the Institutional Review Board (IRB) on _____ (Date). Performing Institution hoids a Federalwide assurance number _____; if not, a Single Project Assurance is required.
  - ☐ Is exempt based on exemption number _____.
  - ☐ Specific plans involving human subjects depend upon completion of survey instruments, prior animal studies, or development of material or procedures. No human subjects will be involved in research until approved by the IRB and a revised Form CSREES-2008 is submitted.

This performing organization agrees to assume primary responsibility for complying with the Federal Policy for Protection of Human Subjects as set forth in 45 CFR Part 46, 1991, as amended, and USDA regulations set forth in 7 CFR 1c, 1992. All nonexempt research involving human subjects must be approved and under continuing review by an IRB. If the performing organization submits a Single Project Assurance, supplemental information describing procedures to protect subjects from risks is required.

SIGNATURE OF AUTHORIZED ORGANIZATIONAL REPRESENTATIVE	TITLE	DATE

Instructions for Completing Assurance Statements and Certifications of Protection from Research Risks

STATEMENT OF POLICY - Institutions receiving CSREES funding for research are responsible for protecting human subjects, providing humane treatment of animals, and monitoring the use of recombinant DNA. To provide for the adequate discharge of this responsibility, CSREES policy requires an assurance by the institution's Authorized Organizational Representative (AOR) that appropriate committees in each institution have carried out the initial reviews of protocol and will conduct continuing reviews of supported projects. CSREES also requires AOR certification by citing a timely date that an appropriate committee issued an approval or exemption.

If a research proposal covers multiple projects in which experimental protocols vary, the AOR must provide documentation of certification, through multiple copies of Form CSREES-2008, by the appropriate committee(s) for each specific protocol utilized in the projects. Examples of multiple project/proposals may include large multi-faceted special grants, multi-institutional consortia, multi-state research projects and some large umbrella Hatch proposals.

Formula funded activities require a certification of action taken by appropriate committees, which necessitates inclusion of the date of the action; the designation of 'pending' is not an option. The designation of 'pending' may be inserted for other grant proposals in lieu of reporting a date of certification that an appropriate committee took action. However, a subsequent approval must be obtained, and a revised Form CSREES-2008 must be submitted before a final award can be made.

A. BIOSAFETY OF RECOMBINANT DNA

If the project involves the use of recombinant DNA molecules, the performing organization shall assume primary responsibility for complying with both the intent and procedures of the National Institutes of Health (NIH), DHHS, Guidelines for Research Involving Recombinant DNA Molecules, as revised:

http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html

This responsibility includes:

1. Ensuring that a standing Institutional Biosafety Committee (IBC) is maintained in accordance with Part IV of the NIH Guidelines and also ensuring that the research plan is reviewed and approved by the IBC prior to commencing substantive work under the project. Actions by the IBC must be documented in Section A of the Form CSREES-2008.

2. Registering with the IBC all experiments involving recombinant DNA molecules conducted with funds provided under the project and complying with the containment requirements specified in Part III of the NIH Guidelines. Records of this research must be kept in a form that is available to CSREES upon request.

In addition, the funded recipient must report the following supplemental data to CSREES and to the reviewing IBC:

a. New technical information relating to risks and safety procedures.

b. Serious accidents or releases involving recombinant DNA.

c. Serious illness of a laboratory worker which may be project related.

d. Other safety problems.

The NIH Guide for Reporting the Occurrence of Serious Adverse Events is published at:

http://grants2.nih.gov/grants/policy/recombinentdnaguidelines.htm

IBC review and approval must be documented in Section A of the Form CSREES-2008. The approval date should reflect a timely review. The approval date reported in section A of the Assurance Form 2008 should not be older than 36 months.

B. CARE AND USE OF ANIMALS

The responsibility for the humane care and treatment of vertebrate animals used in any research project supported with CSREES funds rests with the performing organization. If a project involves animals, except farm animals used for food and fiber research, the personnel identified with the project, and the endorsing officials of the recipient's organization must comply with the Animal Welfare Act (AWA). The AWA (7 USC, 2131-2156; Public Law 89-544, 1996, as amended) and the regulations promulgated thereunder by the Secretary of Agriculture (9 CFR Parts 1, 2, 3, and 4, and subsequent rules and regulations) pertain to the care, handling, and treatment of vertebrate animals held or used for research, teaching, or other activities supported by Federal awards:

http://www.nal.usda.gov/awic/legislat/awicregs.htm

In the case of laboratory animals used or intended for use in research, the institution shall adhere to the principles enunciated in the Guide for the Care and Use of Laboratory Animals, (ILAR, National Academy of Sciences); 1996:

http://www.nap.edu/readingroom/books/labrats/

and to the USDA regulations and standards issued under the public laws stated above. In case of a conflict between the guidelines, the higher standard shall be used.

When domesticated farm animals are used or intended for use in agricultural food and fiber production research, teaching or other activities and housed under farm conditions, the institution shall adhere to the principles stated in the Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching, 1999:

http://www.nal.usda.gov/awic/index.html

which is available from the Federation of Animal Science Societies, 1111 N Dunlap, Savoy, IL 61874.

Prior to commencing research activities with vertebrate animals, all protocols involving animals in CSREES funded projects must be approved by the Institutional Animal Care and Use Committee (IACUC):

http://grants2.nih.gov/grants/olaw/olaw.htm

IACUC review and approval must be documented in Section B of the Form CSREES-2008. The approval date should reflect a timely review. The approval date reported in section B of the Assurance Form 2008 should not be older than 36 months.

C. PROTECTION OF HUMAN SUBJECTS

The performing organization is responsible for protecting the rights and welfare of any human subject involved in CSREES sponsored research and related activities. If a research project protocol involves the use of human

subjects, the institution must agree to comply with the Department of Health and Human Services' (DHHS) regulations on the protection of human subjects:

http://ohrp.osophs.dhhs.gov/polasur.htm

as set forth in 45 CFR Part 46, 1991, as amended (formally adopted as "The Common Rule"), and USDA regulations set forth in 7 CFR 1c, 1992. If a research project protocol involves the use of human subjects, one and only one of the three options outlined under section C of Assurance Form 2008 must be checked.

All nonexempt research protocols involving human subjects must be approved and undergo continuing review by an Institutional Review Board (IRB). If the performing organization qualifies for Federalwide Assurance (FWA) status and has been approved by the Office for Human Research Protections (OHRP), DHHS, then report the assurance number along with the approval date. A list of IRBs with FWA status is available at:

http://ohrp.osophs.dhhs.gov/irbasur.htm

If the performing organization does not have MPA status, a Single Project Assurance (SPA) form may be obtained from OHRP, HHS at:

http://ohrp.osophs.dhhs.gov/humansubjects/assurance/spa.htm

and must be submitted. A SPA is a document to assure compliance and continuing review of the project being proposed, and it is limited in use and duration to this individual research activity. A SPA signed by the IRB Chairperson, AOR, and Project Director of the research project must be submitted. Also, provide additional information regarding the recruitment and selection of subjects, the proposed processes of informed consent and maintenance of confidentiality, and risk and benefit assessments for review by CSREES staff. An institution submitting a SPA may utilize its own IRB or the IRB of a neighboring institution.

The IRB approval date should reflect a timely review. The date reported in section C of the Assurance Form 2008 should not be older than twelve months, because the "Common Rule" requires annual review.

Research activities in which the only involvement of human subjects is in one or more of the following categories are exempt from IRB review:

1. Research conducted in established or commonly accepted educational settings.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless information obtained is recorded in such a manner that human subjects can be identified, and any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk or be damaging.

3. Research not exempt in #2 may be exempt if, in the use of educational tests, the subjects are elected or appointed officials, or federal statutes require that confidentiality will be maintained.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens.

5. Research and demonstration projects which are designed to study, evaluate, or otherwise examine public benefit or service programs.

6. Taste and food quality evaluation and consumer acceptance studies.

A complete explanation of these exemptions can be found at:

http://ohrp.osophs.dhhs.gov/humansubjects/guidance

A project may be funded but temporarily excused from IRB approval if specific protocols involving human subjects depend upon the development of survey instruments, procedures or materials, or completion of animal studies. However, human subjects may not be involved in research activities until IRB approval is obtained and a revised Form CSREES-2008 is submitted.

UNITED STATES DEPARTMENT OF AGRICULTURE
COOPERATIVE STATE RESEARCH, EDUCATION, AND EXTENSION SERVICE

OMB Approved 0524-0039
Expires 03/31/2004

National Environmental Policy Act Exclusions Form

Project Director Name	Institution
Address	

Under 7 CFR Part 3407 (CSREES's implementing regulations of the National Environmental Policy Act of 1969 (NEPA)), environmental data or documentation is required in order to assist CSREES in carrying out its responsibilities under NEPA, which includes determining whether the proposed activity requires the preparation of an environmental assessment or an environmental impact statement, or whether such activity can be excluded from this requirement on the basis of several categories. Therefore, it is necessary for the applicant to advise CSREES whether the proposed activity falls into one of the following Department of Agriculture or CSREES categorical exclusions, or whether the activity does not fall into one of these exclusions (in which case the preparation of an environmental assessment or an environmental impact statement may be required). Even though the applicant considers that a proposed project may or may not fall within a categorical exclusion, CSREES may determine that an environmental assessment or an environmental impact statement is necessary for a proposed project should substantial controversy on environmental grounds exist or if other extraordinary conditions or circumstances are present that may cause such activity to have a significant environmental effect.

Please Read All of the Following and Check All Which Apply

[ ] The proposed activity falls under the categorical exclusion(s) indicated below:

Department of Agriculture Categorical Exclusions
(found at 7 CFR 1b.3 and restated at 7 CFR 3407.6 (a)(1)(i) through (vii))

[ ] (i) Policy development, planning and implementation which are related to routine activities such as personnel, organizational changes, or similar administrative functions
[ ] (ii) Activities that deal solely with the functions of programs, such as program budget proposals, disbursements, and transfer or reprogramming of funds
[ ] (iii) Inventories, research activities, and studies such as resource inventories and routine data collection when such actions are clearly limited in context and intensity
[ ] (iv) Educational and informational programs and activities
[ ] (v) Civil and criminal law enforcement and investigative activities
[ ] (vi) Activities that are advisory and consultative to other agencies and public and private entities, such as legal counseling and representation
[ ] (vii) Activities related to trade representation and market development activities abroad

CSREES Categorical Exclusions
(found at 7 CFR 3407.6(a)(2)(i) through (ii))

The following categories of CSREES actions are excluded because they have been found to have limited scope and intensity and to have no significant individual or cumulative impacts on the quality of the human environment:

(i) The following categories of research programs or projects of limited size and magnitude or with only short-term effects on the environment:
[ ] (A) Research conducted within any laboratory, greenhouse, or other contained facility where research practices and safeguards prevent environmental impacts
[ ] (B) Surveys, inventories, and similar studies that have limited context and minimal intensity in terms of changes in the environment
[ ] (C) Testing outside of the laboratory, such as in small isolated field plots, which involves the routine use of familiar chemicals or biological materials
[ ] (ii) Routine renovation, rehabilitation, or revitalization of physical facilities, including the acquisition and installation of equipment, where such activity is limited in scope and intensity

OR

[ ] Proposed activity does *not* fall into one of the above categorical exclusions
(**NOTE:** If checked, please attach an explanation of the potential environmental impacts of the proposed activity. May require completion of an environmental assessment or an environmental impact statement.)

10.0
SAMPLE PROPOSAL FROM USDA SBIR SOLICITATION

This proposal, which resulted in a Phase I award, was submitted under the Fiscal Year 1999 USDA SBIR Program Solicitation. The sample proposal is provided solely for general guidance. In the original proposal, the cover page was signed by both the project director and authorized organizational official. The social security numbers and budget have been deleted to protect confidentiality.

UNITED STATES DEPARTMENT OF AGRICULTURE
SMALL BUSINESS INNOVATION RESEARCH
SOLICITATION NO. USDA / 02-1

OMB Approved 0524-0025

PHASE I AND PHASE II
PROPOSAL COVER SHEET

Proposal No. (for USDA use only)
Date Received

SUBMITTED	Firm: Lynntech, Inc. Mailing Address: 7610 Eastmark Drive, Suite 202 College Station, TX 77840

Project Title: A New Technique for Ante-Mortem Control of Pathogens in Broilers

Topic No. and Area (check appropriate box; see Section 8.0)

☐ 8.1 Forests and Related Resources	☐ 8.4 Air, Water, and Soils	☐ 8.7 Aquaculture
☐ 8.2 Plant Production and Protection	☐ 8.5 Food Science and Nutrition	☐ 8.8 Industrial Applications
☒ 8.3 Animal Production and Protection	☐ 8.6 Rural and Community Development	☐ 8.9 Marketing and Trade

Amount Requested: ($) $65,000	**Proposed Duration (Mos.):** 6	**Congressional District No.:** 8th

	YES	NO
1. The above concern certifies that it meets the first two criteria of a small business concern as stated in this solicitation (See subsection 2.2).	✘	
2. The above concern certifies that it qualifies as a socially and economically disadvantaged small business as defined in this solicitation (See subsection 2.4). (For statistical purposes only).		✘
3. The above concern certifies that it qualifies as a women-owned small business as defined in this solicitation (See subsection 2.5). (For statistical purposes only).		✘
4. The above concern certifies that the Principal Investigator's primary employment (at least 51%) will be with proposing firm at the time of any resulting award and during the conduct of the proposed research (See subsection 2.2(C)).	✘	
5. The above concern certifies a minimum of two-thirds of the research (phase I) or one-half the research (phase II) will be performed by this firm (See subsection 2.2(D)).	✘	
6. Will you permit the Government to disclose the title and technical abstract page of your proposed project, plus the name, address, and telephone number of the corporate official of your firm, if your proposal does not result in an award, to entities that may be interested in contacting you for future information?	✘	
7. Do you plan to send, or have you sent, this proposal or a similar one to any other Federal agency? If yes, give acronym(s); e.g., DOE, NIH, NSF, etc.		✘
8. Is the organization delinquent on any Federal Debt? (See subsection 5.11). (If yes, attach explanatory information).		✘
9. Will the work in this proposal involve recombinant DNA, living vertebrate animals, or human subjects? (If yes, complete Form CSREES-2008).	✘	
10. Is this proposal a resubmission of a proposal submitted earlier to the USDA SBIR Program (See subsection 3.3(D)). If yes, list the proposal number _____.		✘

By signing and submitting this proposal, the prospective grantee is providing the required certifications set forth in 7 CFR Part 3017, as amended, regarding Debarment and Suspension and Drug-Free Workplace; and 7 CFR Part 3018 regarding Lobbying. (Please read the Certifications and Instructions included in this solicitation before signing this form.) In addition, the prospective grantee certifies that the information contained herein is true and complete to the best of its knowledge and accepts as to any grant award, the obligation to comply with the terms and conditions of the Cooperative State Research, Education, and Extension Service in effect at the time of the award. *Submission of the Social Security Number is voluntary and will not affect the organization's eligibility for an award. However, it is an integral part of the CSREES information system and will assist in the processing of the proposal.

PRINCIPAL INVESTIGATOR	**AUTHORIZED ORGANIZATIONAL OFFICIAL**
Name and Social Security Number*: G. Duncan Hitchens	Name: Oliver J. Murphy
Title: Vice President/Senior Research Scientist	Title: President/Senior Research Scientist
Address: 7610 Eastmark Drive, Suite 202 E-mail: duncan.hitchens@lynntech.com	Address: 7610 Eastmark Drive, Suite 202 College Station, TX 77840
Telephone No.: (979) 693-0017 Fax No.: (979) 764-7479	Telephone No.: (979) 693-0017 Fax No.: (979) 764-7479
Signature: Date:	Signature: Date:

PROPRIETARY NOTICE (IF APPLICABLE, SEE SUBSECTION 5.4)

The following pages (specify) contain proprietary information which (name of proposing organization) requests not be released to persons outside the Government, except for purposes of evaluation.

U.S. DEPARTMENT OF AGRICULTURE
SMALL BUSINESS INNOVATION RESEARCH
PHASE I AND PHASE II
PROJECT SUMMARY*

OMB Approved 0524-0025

FOR USDA USE ONLY			
Program Office	Solicitation No.	Proposal No.	Topic. No

TO BE COMPLETED BY PROPOSER

Name and Address of Firm	Name and Title of Principal Investigator(s)
Lynntech, Inc. 7610 Eastmark Drive, Suite 202 College Station, Texas 77840	G. Duncan Hitchens Vice President/Senior Research Scientist

Title of Project (80-character maximum)

A New Technique for *Ante-Mortem* Control of Pathogens in Broilers

Technical Abstract (200-word limit)

Contamination of poultry and poultry products by *Salmonella* and other pathogens is a serious world-wide problem. One study has shown 1.4 billion dollars in lost productivity, medical expenses, and increased annual production costs in the U.S. caused by *Salmonella* alone. For this reason, methods to control *Salmonella* and other food-borne pathogens on poultry are a research priority. A contributing factor to poultry carcass contamination is the presence of human pathogens throughout the animals' gastrointestinal tract at the time of slaughter. Therefore, measures to reduce pathogens are needed during the pre-slaughter period. This proposal describes a method for intervening in the contamination of broilers by providing drinking water containing a potent disinfectant. The supplemented drinking water will minimize colonization of upper gastrointestinal tract of the chickens, which is an important source of pathogens like *Salmonella*. The disinfectant solution is safe to use on foods and will leave no chemical or environmental residue. A low-cost, miniature device will generate and self-administer the disinfectant to the drinking water without a significant modification to the broiler facility and minimum intervention by the grower. The method is complementary to and easy to integrate with other *ante-mortem* pathogen reduction programs. The Phase I will investigate the feasibility of the method in collaboration with researchers at the Poultry Science Research Center at Texas A&M University.

Anticipated Results/Potential Commercial Applications of Research (100-word limit)

Salmonella contamination of broiler products is a continual problem for the poultry industry. The technology described in this proposal will fill a gap in current broiler management practices and has potential to significantly reduce the incidence of pathogens from final store-ready products. The improved quality of the product will ultimately be passed on to the consumer which can only benefit the poultry industry.

Keywords to Identify Technology/Research Thrust/Commercial Application (8-word maximum)

Food Safety, Broiler Carcasses, *Salmonella*, Pre-Slaughter, Water Disinfection, Feed Withdrawal

*The Project Summary must be suitable for publication by USDA in the event of an award. Do not include proprietary information on this page.

Form CSREES-668 (7/87)

C1. IDENTIFICATION AND SIGNIFICANCE OF THE OPPORTUNITY

Salmonella contamination continues to be a potential problem for the broiler industry. Improvements in processing procedures and sanitary methods within processing plants have allowed for general microbiological improvements in overall carcass quality through the initial stages of processing. However, the incidence of *Salmonella* on broiler carcasses has been shown to increase with successive stages of processing (Lillard, 1989), possibly due to *Salmonella's* ability to firmly attach to poultry tissue. Much research has focused on cecal and intestinal content contamination (Fanelli *et al.*, 1971; Corrier *et al.*, 1990) as the primary source of *Salmonella* within chickens. However, recent reports have shown the crop may potentially serve as an important source of *Salmonella* contamination on broiler carcasses within some processing plants (Hargis *et al.*, 1995). A higher incidence of *Salmonella* in crops than in ceca has been reported, along with a higher incidence of ruptured crops than ruptured ceca during commercial evisceration. In addition, colonization of the crop by *Salmonella* can increase as chickens near processing age (Humphrey *et al.*, 1993; Ramirez, *et al.*, 1997). Consequently, the crop is now considered an important critical control point for reducing *Salmonella* contamination of broiler carcasses.

Our goal is to develop a method for intervening in the contamination of the crop as broilers reach marketable age. We will demonstrate a new bird watering method that provides broilers with oral antiseptic solutions containing dissolved ozone. The concept is shown in Figure 1. The aim is to provide a drinking solution that minimizes bacterial colonization of the crop and upper gastro intestinal tract of the chickens at the critical pre-slaughter time (See Figure 2). Recently, ozone solutions have been studied as an antiseptic for intestinal disorders in humans. This research has shown that ozone solutions are safe when taken internally and that they offer a high potential for minimizing bacterial colonization of the digestive system. The benefits of ozone include its high solubility in water (ten times that of oxygen) and a strong capability to eliminate many different kinds of microorganisms. Yet ozone does not persist, it rapidly decomposes into oxygen leaving no harmful residues. In 1997, ozone was conferred GRAS (Generally Recognized as Safe) status for use as a disinfectant on foods by the Food and Drug Administration (Majchrowicz, 1998; Federal Register, 1997; Graham, 1997; Anon, 1997). Ozone has been used safely and effectively to purify drinking water for nine decades. It also has GRAS status for use in bottled water.

We will use a unique miniature ozone generation-injection device that connects directly into existing bird waterers. The method has been devised to be minimally intrusive, so that the operator can temporally attach the ozone generator onto water lines close to the point of consumption through a quick-connect fitting. The device is designed for continuous operation during the time of feed withdrawal, leading up to crating and transportation. The device can be quickly removed and transferred to other rearing areas as required. The projected cost of the miniature ozone generator-injector is $50-100. The ozonation hardware we will use is based on existing designs (Hitchens, *et al.*, 1994; Murphy, *et al.*, 1994; Murphy & Hitchens, 1995; Anon, 1997b; Murphy & Hitchens, 1998); therefore, the proposed equipment build-up needed for all aspects of this project will be accomplished in a timely manner with little or no requirement for ozone technology development.

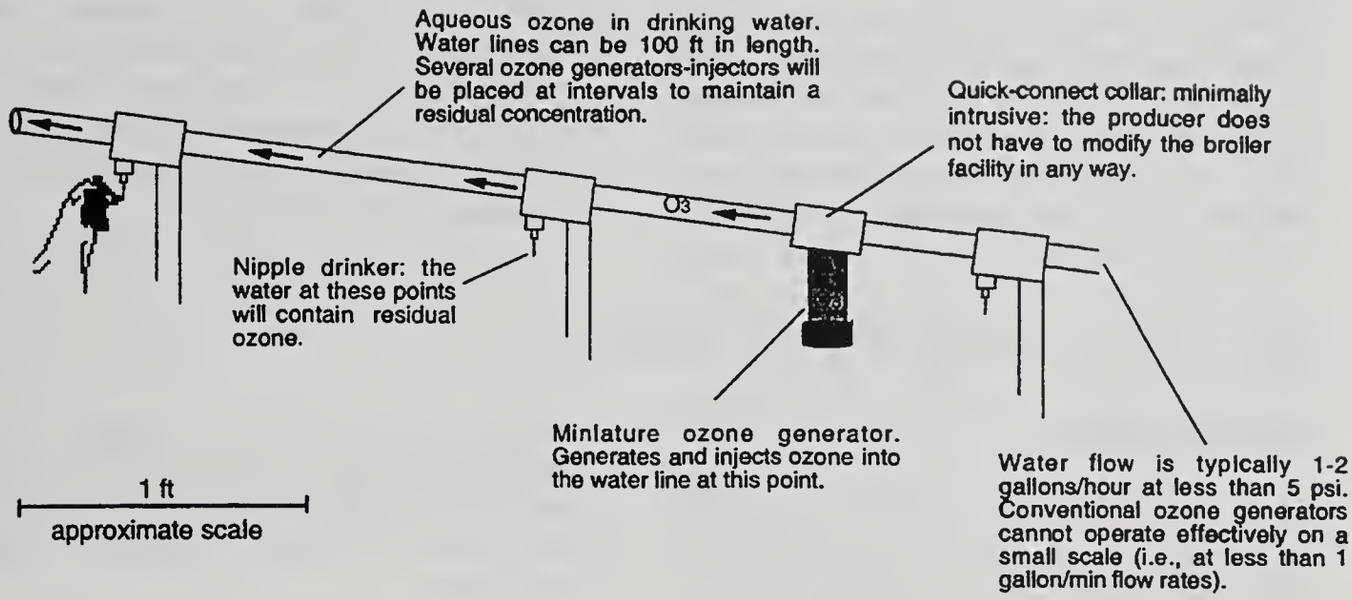

Figure 1. The concept for providing dissolved ozone for broiler drinking water. Ozone is generated in a unique electrolysis process. The generators also inject ozone into the water line without interfering with the normal operation of the waterer. Ozone can be effective against *Salmonella*, *Campylobacter,* viruses and other emerging pathogens and offers the potential for decontamination of ingesta in the crop and other regions of the GI tract. Self-disinfection of the water lines and watering equipment is also provided and ozone can be applied directly to incoming municipal water supply or well water; ozone is non-reactive with chlorine. The miniature ozone generators are expected to cost $50-100 per unit.

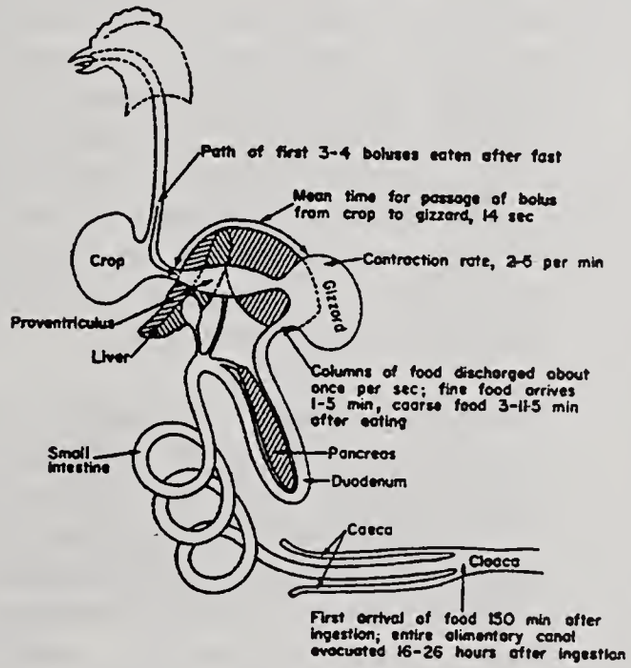

Figure 2. The Phase I goal is to demonstrate that ozonated water can be ingested by broilers to reduce *Salmonella* colonization of the crop. Ozone solutions are used as a therapeutic agent for intestinal disorders in humans and will not leave harmful residues in the bird or in water. The presence of dissolved ozone at mg/L concentrations is not easily discernible in drinking water. Therefore, the ozonation method should not affect the palatability of the drinking water. Diagram adapted from Malden *et al.*, 1979.

During this project, a subcontract will be made to Dr. Billy M. Hargis, Professor, Department of Veterinary Pathobiology, College of Vet. Medicine, Texas A&M University. Dr. Hargis is director of a leading research laboratory in poultry diseases and has studied *Salmonella* contamination of the crop. The blend of technical competencies between Dr. Hargis and Lynntech, Inc. provides a very effective team with strengths in oxidative disinfection coupled with a thorough understanding of microbial diseases. The background section that follows describes relevant literature on broiler carcass contamination by *Salmonella* and other pathogens. The section also discusses the current status of ozone in the food industry, as well as research on ozone solutions for internal treatments in humans.

C2. BACKGROUND AND RATIONALE

BACKGROUND

(I). Contamination of Broiler Carcasses

The prevalence of *Salmonella* and *Campylobacter* on retail poultry carcasses remains a significant public health concern. The Public Health Service/Centers for Disease Control report that each year millions of Americans suffer illness caused by foodborne infection. *Salmonella* and *Campylobacter* together are thought to be responsible for the majority of acute cases of gastroenteritis (Mulder, 1995). The global association between the occurrence of these genera of foodborne pathogens and contamination of poultry are well documented in the literature (Lahellec & Collin, 1985; Marinescu *et al.*, 1987; Lammerding *et al.*, 1988). In an attempt to characterize the *ante-mortem* levels of pathogens in commercial broilers, Jacobs-Reisma and coworkers (1994) found that, of over 180 flocks surveyed approximately, 27% contained *Salmonella* and 82% contained *Campylobacter*. More recently, Ramirez and coworkers found from 19-36% of commercial broilers (n=100) contained *Salmonella* in the crops and ceca just prior to slaughter (1997). A 1983 survey of poultry carcasses showed that of 215 carcasses that exited the chiller bath at the slaughter facility, 11.6% were positive for *Salmonella* (Campbell *et al.*, 1983). Stern and Line (1992) found *Campylobacter spp.* by extensive analysis in 98% of retail packaged broilers. The correlation of infected birds to contamination of the final product seems to, therefore, be a linear relationship, warranting intervention strategies at *ante-mortem* stages of production.

Much of the research regarding the source of pathogen contamination of poultry has focused on cecal and intestinal content contamination (Corrier *et al.*, 1990), with the presumed major reservoir of pathogens being expelled onto the carcass via emptying of the cecal contents during processing (Fanalli *et al.*, 1971, Snoeyenbos *et al.*, 1982). However, recent reports have identified the crop as a significant harbor of pathogenic bacteria and therefore, this upper G.I. organ may be serving as an additional source of contamination on broiler carcasses (Hargis *et al.*, 1995; Ramirez *et al.*, 1997). Supporting evidence for this hypothesis may be found in a study by Hargis and coworkers who found that the incidence of crop rupture in commercial evisceration is higher than cecal rupture (1993).

Of additional concern to the broiler industry is the increase in recoverable *Salmonella* in the crops of broiler chickens as the feed withdrawal time period is increased prior to shipment of the birds to the slaughter facility (Humphry *et al.*, 1993; Ramirez *et al.*, 1997). These data further suggest that *ante-mortem* management practices may influence the degree of carcass contamination at slaughter. Indeed, this was the

approach used by the developers of competitive exclusion (CE) innoculums for chicks (i.e., Preempt, which was developed by USDA scientists and MS Bioscience), which utilizes indigenous gastrointestinal microflora to compete for resources and therefore, exclude the proliferation of more harmful, pathogenic bacteria (Byrd *et al.*, 1998). It is clear that the period of feed withdrawal is coupled with consumption of the litter, a harbor of *Salmonella* that contaminates both the ceca and crop (see Table 2).

Table 2. Effect of Feed Withdrawal on *Salmonella* Colonization of the Crop and Ceca in Market Age Broiler Chickens (Adapted From Ramirez, *et al.*, 1997).

Expmt.	Treatment*	Positive crops/ total	Positive ceca/ total
1	FF	4/14 (29%)	9/15 (60%)
	WF	12/15 (80%)	14/15 (93%)
2	FF	3/25 (12%)	11/25 (44%)
	WF	22/25 (88%)	11/25 (44%)
3	FF	3/20 (15%)	7/20 (35%)
	WF	16/20 (80%)	15/20 (75%)
4	FF	5/20 (25%)	14/20 (70%)
	WF	16/20 (80%)	20/20 (100%)
5	FF	19/100 (19%)	25/100 (25%)
	WF	36/100 (36%)	31/100 (31%)

*FF = full-fed, WF = feed withdrawal (18 h withdrawal in Experiments 1 to 4, 8 h withdrawal in Experiment 5). Broilers were orally challenged with 1 x 10^8 *Salmonella entertidis* at 6 wk of age and samples were collected at 7 wks of age (Experiments 1-4). Naturally occurring *Salmonella* were cultured from a commercial broiler house at 7 wk of age in Experiment 5.

The CE approach is excellent for continuous control of *Salmonella* infection of birds throughout the growing period for broiler chicks. However, the most effective location for CE microbes is in the lower GI tract, including the cecum and intestines. By adding an orally administered biocide/biostat through the drinking water during feed withdrawal, the levels of litter-derived *Salmonella* and *Campylobacter* can also be controlled in the upper GI region (Barnhart *et al.*, 1998a, 1998b), thus allowing for the two technologies to work together. The drinking water oxidant proposed in this study will not leave any residue in the bird, its urine or litter, making it an inexpensive, safe, environmentally and consumer friendly alternative to organic acids, salts and antibiotics. The short half life of aqueous ozone and reactivity will mean that ozone and competitive exclusion will work in tandem, at both anatomical locations responsible for harboring pathogens.

(II). Ozone as a Disinfectant

Dissolved ozone is a highly efficient disinfectant-sterilant for all classes of microorganisms (Rose *et. al.*, 1994; Foller, 1982, Takahashi &Nakai, 1994; Zhouu & Smith, 1994; Shen & Ku, 1995; Andreozzi *et. al.*, 1995; Langlais, 1991). The effectiveness of ozone gas as a disinfectant is shown in Table 3. The Table shows ozone to be a non-selective agent for a wide range of bacteria, spores, and viruses. Over the last 100 years ozone has been used in Europe as a disinfectant for water. Ozonation, unlike other chemical treatments, leaves no residual chemicals in the water stream i.e., ozone is a non-persistent chemical. After it reacts, it breaks down to form oxygen gas.

Table 3. Disinfection Features Of Ozone (Nebel & Nezgod, 1984)

Organisms	$C_{t99:10}$
Escherichia coli	0.001
Streptococcus faecalis	0.0015
Mycobacterium tuberculosis	0.05
Polio virus	0.01
Bacillus megaterium (spores)	0.1
Entamoeba histolytica	0.03

$C_{t99:10}$ = Residual ozone concetration in mg/L for 99% destruction in 10 minutes

Temperature = 10 - 15 ÞC **pH** = 7.0

(III). The Use of Ozone in the Food Industry

In recent years, there has been a drift away from conventional chlorine-based water treatments and aqueous ozone technology is beginning to emerge as an attractive alternative. One field in which ozone technology is coming to the fore is in the food industry. Ozone was recently given the status Generally Recognized As Safe (GRAS) by the Food and Drug Administration for use in the food industry. This was accomplished after an expert panel, assembled by the Electric Power Research Institute (EPRI), concluded ozone is safe and a necessity as a sterilant in the food industry (Anon., 1997). The streamlined approach to granting of GRAS status was announced by the FDA in 1997 (FDA, 1997).

Ozone has also been demonstrated to be effective in reducing microbial counts in several areas: increase storage life of meat, fruit and cheeses (Easton, 1951), and to control post-harvest decay of table grapes (Sarig *et al.*, 1996). Ozone is also more effective at disinfecting *Salmonella, Giardia, E. coli* and *Cryptosporidium* than existing chlorine-based technologies (Agricultural Technology Alliance, 1998). Ozone is also capable of degrading a wide range of organics, including pesticide residues (Food Industry Currents, 1997). Ozone has been demonstrated to be an effective food germicide and can significantly reduce the numbers of pathogens on poultry (Dickson, *et al.*, 1992; Yang and Chen, 1979a, Yang and Chen, 1979b). The use of aqueous ozone has been shown to be effective at eliminating both gram negative and gram positive microflora from the surface of poultry meat.

(IV). The Use of Ozonated Water in Eliminating Oral and GI Tract Pathogens

Ozone is approximately 10 times more soluble in water that oxygen. Ozonated water is a common item found in European dental surgeries. In a comprehensive study (Turk, 1985; Filippi, 1997) it was found that ozonated water, when administered orally, promoted hemostasis, enhanced local oxygen supply, and inhibited bacterial proliferation. Ozonated water has also been used as a oral rinse during and after tooth extraction (Sunnen, 1987). Ozonated water has also been used in the treatment of oral cavity infections such as thrush, periodontal disease, and tonsillitis (Silva & Wong, 1998).

Peroral ingestion of ozonated water has also been shown to be effective at treating gastro intestinal problems. Problems such as gastritus or gastric carcinoma have been successfully treated with ozonated water. Androsov *et al.* showed that ozonated water was effective at destroying *Heliobactor pylori* in the patients stomach without causing any side effects. Peroral ingestion of ozonated water has also been used in the treatment of chronic intestinal or bladder inflammation. Ozonated water bubbled into warm baths has been shown to provide stimulation of the local circulation and disinfection action to varicosities, peripheral circulatory disorders, and dermatological conditions (Rilling & Viebahn, 1987). In most of these cases, the ozonated water is prepared using a medical ozone generator which uses pure oxygen instead of air as the gas feed. DI water was borbotaged by the ozone oxygen mixture for 10 minutes then immediately administered to the patient in 100 mL portions.

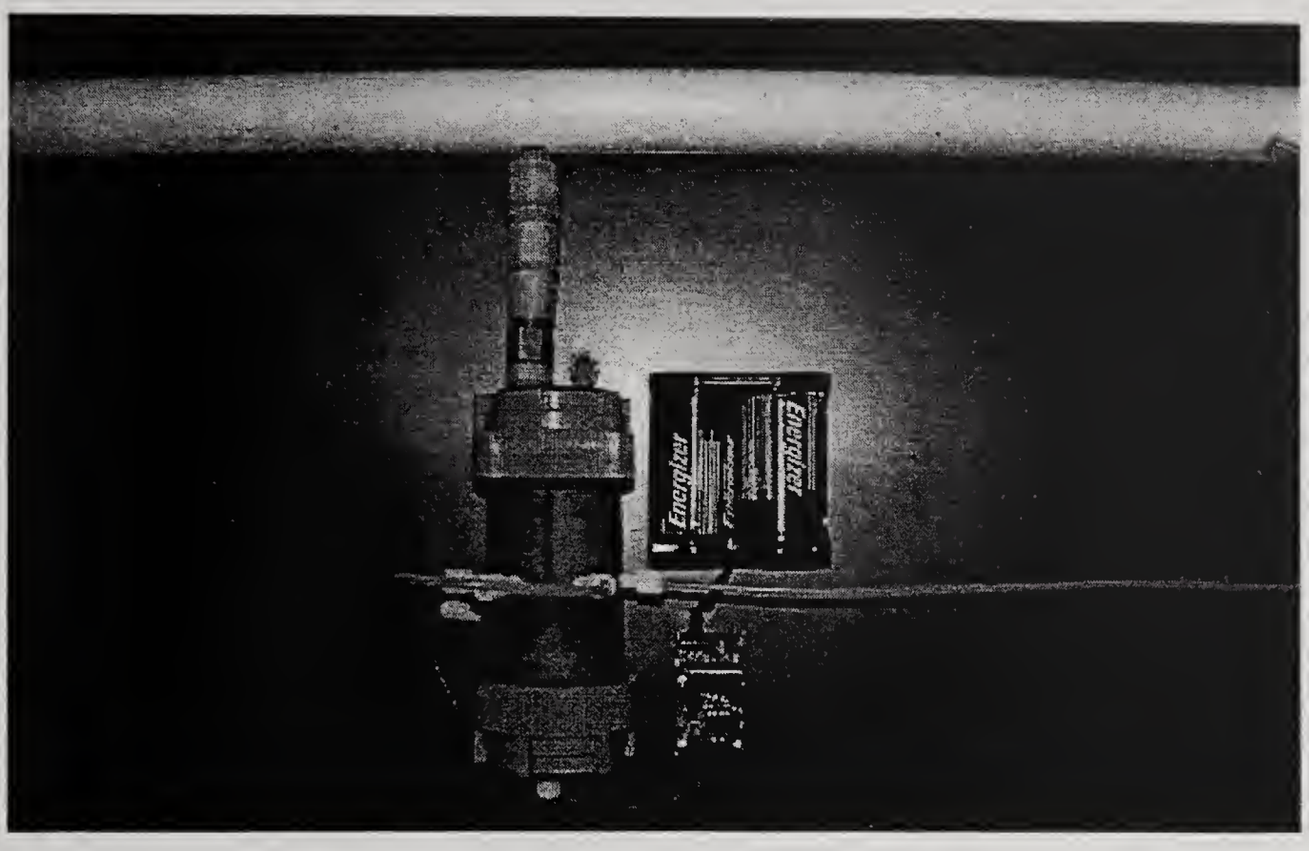

Figure 3. Photograph of a 20 mg/hr electrochemical O3 generator. Our knowledge of the engineering, materials, and safety aspects of O3 systems is extensive. The ozonation hardware we proposed will be based on existing designs; therefore, much of the proposed equipment build up described in Task 1 of this proposal will be accomplished in a timely manner with little or no requirement for ozone technology development. The electrochemical unit shown in this photograph can be readily adapted into "nipple" –or- "bell" type waterers. Operation aspects of this unit are depicted in Figures 4 and 5.

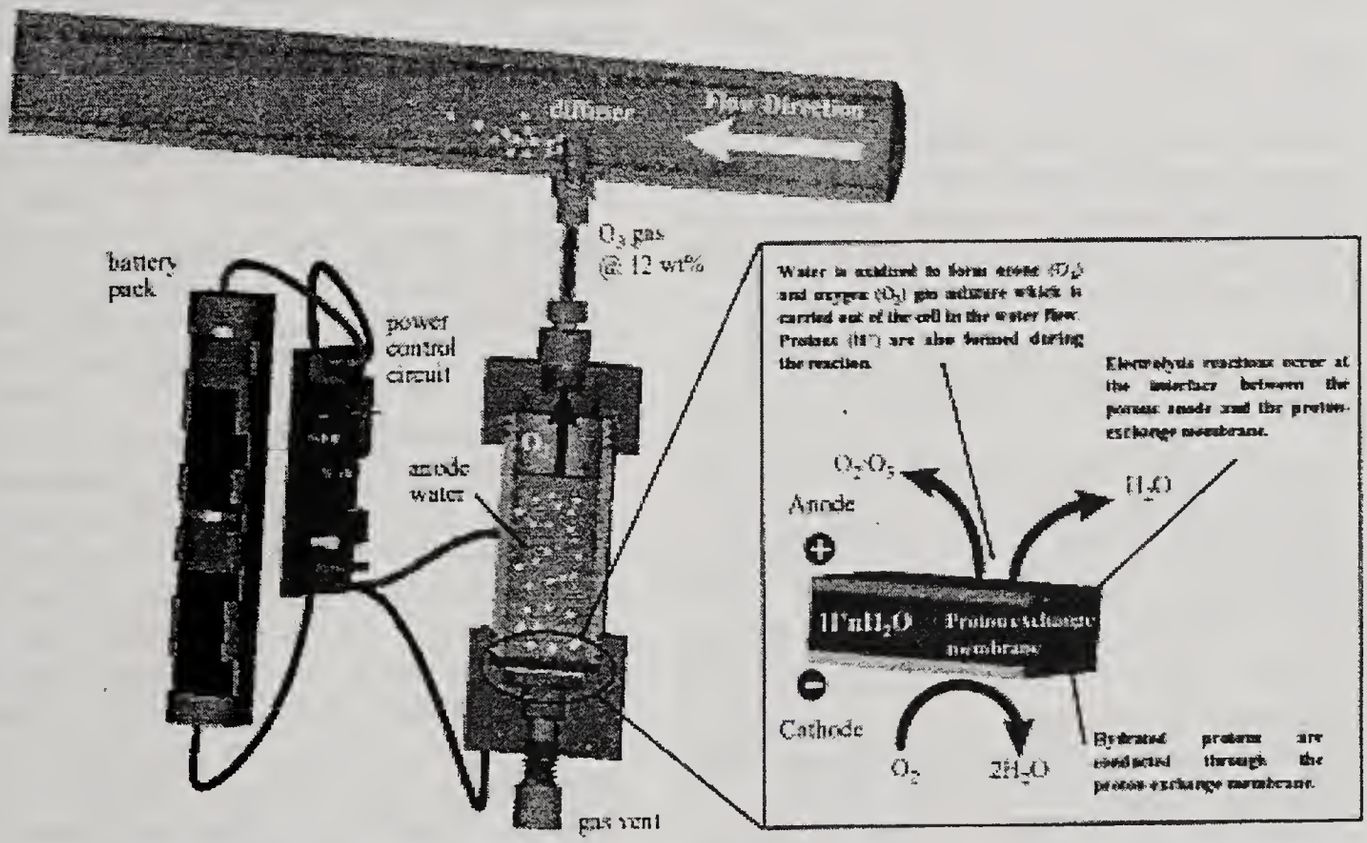

Figure 4. Component layout diagram of the electrolysis apparatus in Figure 3. To minimize equipment costs, *operation does not require valves or pumps*. The expected cost to manufacture is less than $100 each. The unit is entirely self-contained with its own power supply, water management, and waste gas handling systems.

Figure 5. Principle of electrochemical ozone generation in a proton exchange membrane.

RATIONALE

This section describes the new device for ozone generation that will be used for providing ozonated drinking water for broilers. The method uses a unique electrolysis (i.e., electrochemical) process that has been pioneered by Lynntech, Inc., (Hitchens, *et al.*, 1994; Murphy, *et al.*, 1994; Murphy & Hitchens, 1995; Murphy & Hitchens 1998) and is currently being commercialized (Anon, 1997(b)). A photograph of one of our devices is shown in Figure 3. Figure 4 gives the layout of the hardware. Sources of electrical power and water are the only requirements for producing ozone by this method. This method has many unique cost and process advantages for use in small sized water lines. As discussed later, conventional ozone generators (either corona discharge or UV lamps) do not scale down and are impractical for low flow rate water treatment regimes (i.e., for treating 500 L/hr or less).

(I). Principle

Figure 5 depicts the principle of Lynntech's electrochemical ozone generation process. In the process, water is electrolyzed at the anode (a metal oxide electrode), to form a mixture of O_2 (equation 1), and O_3 (equation 2).

$$2H_2O - 4e^- \rightarrow O_2 + 4H^+ \quad E° = 1.23V \quad (1)$$
$$3H_2O - 6e^- \; O_3 + 6H^+ \quad E° = 1.51\ V \quad (2)$$

The current we apply is typically 1.5-2.0 A/cm^2 of electrode area. The cell voltage is 3.5 V. Approximately 15% by weight of the resulting gas is ozone. The remainder is oxygen. The O_3 and O_2 partition between the liquid and gas phases as they are formed. Protons formed at the anode are conducted to the cathode through a Nafion proton exchange membrane which serves as a solid polymer electrolyte (i.e., the proton conducting pathway between the two electrodes). The use of a Nafion membrane eliminates the need for a liquid electrolyte and acts as a separator between the anode and cathode compartments. Nafion is a fluoropolymer and displays a very high resistance to chemical attack by ozone. The preferred cathodic reaction is the reduction of oxygen, where air serves as the oxygen source. This reaction is represented by equation (3).

$$O_2 + 4H^+ + 4e- \; 2H_2O \quad E°=1.23\ V \quad (3)$$

Specialized gas diffusion electrodes are required for the oxygen reduction reaction to occur efficiently. The layer of bonded carbon particles serves as a three-dimensional microporous structure for diffusion of the reactant gas (air) into the electrode structure.

(II). Performance Characteristics

This electrochemical ozone generator is ideal for small capacity drinking water applications. Some of its characteristics, compared to alternative ozone generation methods are given in Table 4. The gaseous output of up to 15 percent ozone by weight (wt%) is high relative to the competing methods. This means that adequate levels of ozone can be dissolved in solution (see Table 4). We anticipate a concentration of 2-5 mg/L can be readily achieved. This concentration cannot be achieved with either CD or UV generation methods. Another key advantage is that the anode chamber, in which the ozone gas is produced, acts as a self-pressurizing chamber. When the output gas line from the generator is connected to a water line, the gas will be generated up to the pressure of that water line, causing the ozone gas to be directly injected into the line without any additional equipment. Also, the ozone injection method does not affect the water pressure of the line. Line pressure is precisely regulated at around 1-1.5 psi for nipple-type bird waters. The injection

system we use will therefore not interfere with the normal operation of the waterer .

Table 4. Comparison of Ozone Generation Processes.

Ozone Source Small Size Systems	Energy (kWh/lb O_3)	Cg (mg/L air)	Cw (mg/L water)
Air Fed Corona 0.5 wt %	30	6.8	2.4
UV Lamp 0.1 wt%	30	1.3	0.5
Electrochemical 12 wt %	25	183*	42.3

*mg/L oxygen

O_3 solubility (C_W) was determined from Henry's law: P = HC, where: P = gas partial pressure above the liquid (mg/L air), H = Henry's law constant (2.59 mg gas/L air per mg gas/L water at 20C), C = concentration of gas in the liquid (mg/L). Much higher dissolved O_3 concentrations are possible with electrochemically generated higher O_3 gas concentrations, assuming Henry's Law relationship is obeyed. In practical situations, C_W is always below the Henry's law prediction due to factors like contacting efficiency. Normally it is difficult to achieve > 2 ppm dissolved ozone using air fed corona discharge units.

(III). Comparison of the Disinfection Capabilities of Electrochemical Versus Corona Discharge Ozone Generators

Corona discharge (CD) is the conventional process for generating ozone gas, but it cannot be used for the type of small scale application described in this proposal. In the corona discharge process, oxygen present in the air, or in an enriched feed gas, is converted from diatomic oxygen (O_2) into ozone (O_3) through an electrical discharge. The air passing into these units must be dried to a dew point of minus 50°C or below. Corona discharge systems do not scale down and there is a price barrier to using CD generators on a small scale. Four of the leading manufacturers of small corona discharge generators are Azco, Purezone, Ozotech and Clearwater Tech. Even the smallest units in the product lines of these companies generate at least 10g/day of ozone, far in excess of the needs of small water feed lines. Ozone generators typically cost $400-450, but they must be used in combination with an air dryer, which itself costs $500-700 depending upon the manufacturer. Also, a method must be used to introduce ozone into the water. A venturi can be used but this is only practical at fast flowing water sources (a venturi uses the water flow to create a negative pressure dissolving ozone in water). If an air pump is used to engage the ozone, the cost will be at least $100 higher again. Therefore, the smallest CD ozone generation system will cost in excess of $1,500 uninstalled.

Small ozone generators (<1 lb/day) also lack the performance necessary to achieve adequate dissolved ozone concentrations. "Industrial scale" CD systems (i.e., those producing 1lb of ozone per day or more) are energy efficient and produce relatively high concentrations of ozone in their output streams (2 wt % for an air-fed corona, or 6 wt % for an pure oxygen-fed corona). However, the smaller versions do not come close to meeting these output concentrations. The significance of being able to generate high ozone concentrations in the gas phase is illustrated in Table 4. The dilute ozone gas streams from CD units cannot easily be engaged into solution, resulting in dissolved ozone concentrations that are too low for many disinfection applications. Finally, in air-fed corona discharge units NOx is formed as a by-product. Nitric acid builds up in the unit. Without frequent (i.e., weekly) maintenance and cleaning these units fail. Furthermore, nitric acid is often formed in the water being treated.

Ozone can also be generated by UV bulbs operating at 185 nm. These systems are, however impractical for water treatment because of their low output concentrations (0.1 wt %).

In summary, electrochemical ozone generators are superior because air drying is not required, the formation of nitric acid is eliminated and, they generate high concentrations of ozone compared to conventional methods for ozone generation.

(IV). Installation and Operation Considerations

This section discusses issues related to how the ozonation method will be operated in a production facility. Two types of watering systems are commonly used in broiler facilities. Nipple drinking facilities are replacing the hanging bell-type waterer. Water supply should be arranged to minimize bird effort in accessing it (May *et al.*, 1997). Most hanging bell waterers are forty inches in circumference with the capability of handling up to one hundred birds at one time. Nipple drinkers are spaced about 8 inches apart and generally can handle 15 birds per nipple. Both types of waterers can be hung from a winch system, allowing adjustments as the birds get older and elevation to the ceiling for easy bird catching and litter removal.

The micro-ozone generators will inject ozone into the water lines connecting the waterers and nipple fittings. Attachment to the line will be via a quick connect making removal easy, enabling the devices to be moved to waterers serving other grower houses. We estimate that a 20 mg O_3/hour capacity should be the optimal capacity for the lines feeding the bird waterers. Generator size is determined by the rate of water flow (typically 10L/min) and the ozone residual needed for adequate killing; 1 mg/L is more than sufficient to achieve a high level of disinfection (see Table 2). Therefore, the 20 mg/hr capacity provides a dose sufficient to meet the 10mg/L residual level, with 10 mg/L of excess capacity for O_3 losses that will occur down-stream from the injection point. A number of devices will be placed at intervals along the line to keep the dissolved O_3 levels in the desired range. Each micro ozone generator will produce approximately 100 mL of ozone-containing gas per hour. The gas is introduced into the line through a diffuser for high contacting efficiency. An outlet check valve collects and releases small amounts of excess gas from the line.

The small size of the generators will have minimal environmental impact. Ozone is a toxic gas with a recommended maximum exposure limit of 0.1 ppmV (or 0.04 µg/L). However, broiler facilities are large (>6,000 m^3) and extremely well ventilated, with large air-handling equipment. Under the worst case hypothetical situation, where 6-8 micro-ozone generators were venting all their gaseous output directly into the house rather than into the water line, the ozone levels would not exceed safe limits, even if the ventillation was turned off. There also is little potential for any ozone off gas to emanate from the drinking water. Typically it is impossible to detect any off gas from solutions containing 1 mg/L or less of dissolved ozone.

C3. RELATIONSHIP WITH FUTURE RESEARCH AND DEVELOPMENT

In performing SBIR projects, Lynntech follows a well defined plan of activities to develop a concept and to successfully transition it to a commercial prototype. The goal of Phase I is Proof of Concept, which includes several key elements: (i) articulate the scientific basis; (ii) confirm critical assumptions; and (iii) identify key issues requiring resolution during Phase II. Phase II consists of two major elements. The first one focuses on Technical Feasibility which leads to assembly and testing of a scaled-up laboratory model. The specific features are: (i) resolve major research issues; (ii) establish formulation requirements; (iii) design

formulation process; and (iv) perform definitive testing. The second major element of Phase II activities is Development of a Formulation and Process Prototype. Specific features include: (i) make needed improvements in materials, components, and processes; (ii) establish basis for final scale-up; (iii) optimize product features using models, analyses, and tests; (iv) confirm formulation process; and (v) fabricate prototype or pilot process. The work plan described in this proposal is based on principles, methods, and company policies leading to successful product development.

(I). Mini Ozone Generators: Equipment and Operating Costs

Using our extensive experience in ozone generation and use applications, the cost factors for implementing and using ozone can be realistically defined. Lynntech has a pre-commercial, milligrams/minute electrochemical ozone generation unit. The power required to generate the 20 mg/L of ozone that will be generated in each cell is 0.7 Watts. This low power demand allows the cells to be run for a cost of only a fraction of a cent. The low power consumption allows the ozone generators to operate on AAA or AA rechargeable batteries. It is projected that when the milligrams/minute ozone generation units can be produced in multiples of 10-100 units at a time, the cost will be about $85 each.

This low cost can be achieved because the unit, shown in Figure 3, will only need 5 components for it to operate. Injection molding allows the cell components to be mass produced for little cost while the screw end fittings are available from commercial suppliers and can be bought at low cost when purchased in bulk quantities. The electrode ensemble requires only small amounts of catalyst coated expanded metal and membrane for the cell to operate. The life expectancy of the ozone generation unit, when run on a continuous basis, is a minimum of 5 years. Based on these known factors at the present time, the economics of this technology are extremely favorable.

The use of aqueous ozone to eliminate the contamination in the crop will have many economic benefits to the poultry industry. Eliminating potential pathogens in poultry products will have only positive effects on the broiler retail markets. Through the Phase I feasibility study and Phase II prototype development Lynntech will obtain the intellectual property necessary to push this technology to Phase III and commercial development. Lynntech will work with the necessary broiler industries to fully develop this treatment system. The outcome of this endeavor will make processing poultry safer for the consumer.

C4. PHASE I TECHNICAL OBJECTIVES

The overall objective of this project is to demonstrate the effectiveness of ozonated water, generated under pressure by small, portable electrochemical ozone generators, to decrease or control *Salmonella* bacterial populations in the crops of market age broiler chickens during feed withdrawal. A bench-scale mock-up of the portable electrochemical devices will be plumbed into a research-sized nipple water drinker. Birds will be gavaged with a known amount of *Salmonella* prior to feed withdrawal and the crops and ceca will be evaluated microbiologically.

The work involving the design of the ozone generation device and bird drinking apparatus will be performed at Lynntech, Inc. The apparatus will be moved to the Poultry Science Center at Texas A&M University for experiments involving ozonated water and

market broilers in collaboration with Dr. Billy Hargis.

Experiments planned in the Phase I research and development efforts are designated as four separate and distinct tasks. The tasks in addition to the methods and techniques used are described in detail below. These tasks are designed to answer the following questions:

Will broilers drink water with modest levels of dissolved aqueous ozone?
What ozone concentrations provide an acceptable level of pathogen reduction?
Can these levels of ozone be maintained in nipple watering pipes?

C5. PHASE I WORK PLAN

Task 1. Assembly and Testing of the Broiler Watering System.

The first task will focus on assembly of a test system that will allow for delivery, dissolution and distribution of ozone within the water lines of a nipple drinker. A Lynntech model 724 ozone generator will be made available for these experiments. In Task 1, we will establish ozonation parameters for the watering system to be used in Tasks 2 and 3. This will be accomplished using a laboratory test fixture comprising a length of pipe of the same materials with an internal diameter as the one at the Poultry Science Center (PSC) with a collar and ozone generator-injector attached to one end. The attachment will include diffuser, baffle, gas collector and gas release check valve. The ozone generator will be powered by a variable D.C. power supply. The water line will contain sampling points at increasing distances away from the injection point. Water flow and water pressure will be within the range used at the PSC. Using experimental variables, such as water flow rate, electrolysis current, type of diffuser, etc., will establish how to operate the system in the poultry facility such that ozone levels can be controlled and maintained in the range needed for the Task 2 and 3 studies. By establishing an ozone concentration profile down-stream from the injection site, we can gain an understanding of how far apart the injection sites should be for various operating regimes. The concentration of dissolved ozone will be measured using a Shimadzu (Kyoto, Japan) Model UV 2101 PC double beam spectrophotometer within a flow cell at 254 nm or indirectly by oxidation of indigo blue dye.

We are well aware of the potential hazards associated with the use of ozone (e.g. exposure through inhalation due to off gases). Safeguards to deal with these issues are built into each piece of equipment constructed. Safeguards include the unit enclosures which will be fitted with ozone destruct units to take care of potential leaks. If concentrations are found to exceed expected levels, point source pick-ups with destruct units could be utilized.

Lynntech is well equipped to deal with these or any other ozone issues as they arise. With increasing demand for ozone equipment, Lynntech has been constructing, using and testing safe ozone equipment for more than 5 years. Of which, a great deal of research has gone into perfecting the generation process.

Following these experiments, an appropriately designed system will be assembled at the PSC.

Task 2. Assessment of Bird Acceptability, Palatability of Dissolved Ozone.

The studies in Task 2 will be performed in a test grower house at the PSC through Dr.

Billy Hargis and Dr. David Caldwell, Departments of Veterinary Pathobiology and Poultry Science, Texas A&M University. Seven week-old broilers (n=160) will be obtained from a local commercial grower and placed into four pens giving a commercially-simulated bird density of 40 birds per pen. The pens will be equipped with filtered air and the floors will be covered with wood shavings as litter. All birds will be given a standard broiler ration and water via nipple drinkers *ad libitum* for two days, after which the average pen weights will be recorded. On the third day, the nipple drinkers of three pens will be modified to obtain the following treatments: Pen 1, control (no treatment of water); Pen 2, low dissolved ozone concentration in water (0.1-1 ppm); Pen 3, high concentration of dissolved aqueous ozone (1.0-5.0 ppm), and; Pen 4, water with commercial grade oxygen gas bubbled through at a flow rate approximately equal to the rate of ozone delivery.

For the three weeks that follow, the birds will be evaluated for water consumption by metering the return water feed from the municipal water supply at the test barn. This will be done after the first step-down water pressure regulator so as not to interfere with ozone dissolution. An indirect measurement of water consumption will be made by measuring average in body weight gain (feed conversion) as it is affected by water consumption. Each pen of birds will be weighed at the end of the week (total of 4 times in three weeks). This approach will also allow for determination of any significant water refusal (palatability) issues based on the presence and concentration of ozone. We expect that there will not be any refusal and that ozonation may actually enhance water consumption based on ozone's ability to eliminate off tastes and odors in municipal water supplies.

Task 3. Evaluation of the Disinfection of *Salmonella* in Broiler Crops and Ceca.

(I). Experimental infection with *Salmonella enteritidis*.

A primary poultry isolate of *S. enteritidis*, phage type 13A, will be obtained from the USDA National Veterinary Services Laboratory. This isolate is resistant to the antibiotic novobiocin, No. n-1628 (25 µg/mL) and has been selected for resistance to nalidixic acid, No. n-4382 (20 µg/mL). For these studies, *S. Enteritidis* will be grown according to the method of Lee and Falkow (1990), allowing for attainment of log-phase growth. Cells will be washed three times in distilled water by centrifugation (100 x g) and quantified spectrophotometrically to a stock concentration of approximately 1 x 10^9 cfu/mL in distilled water, using a standard curve generated from comparison of multiple spread platings and optical densities, and then diluted to challenge concentrations (Ramirez *et al.*, 1997).

(II). *Salmonella* Recovery from Crops and Ceca.

Commercial broiler chickens (n=160), previously shown to be *Salmonella* free, will be obtained at 6 wk of age from a commercial broiler grower for use in the experiments. For the Task 3 experiments, broilers will be housed in floor pens (18.6 m^2) on new pine shavings in an isolation facility located near the Texas A&M University College of Veterinary Medicine through Dr. Hargis. Broilers will be provided *ad libitum* access to a corn-soybean ration and water for two days. A total of 80 birds will be then be challenged with 1 x 10^8 cfu *S. enteritidis* per milliliter saline by oral gavage.

Table 5. Summary of the Treatment Groups to be Studied in Task 3.

(n=20)	Salmonella challenged?	Aqueous ozone in drinking water?	Feed withdrawal?
Group 1	+	+	+
Group 2	+	+	-
Group 3	+	-	+
Group 4	+	-	-
Group 5	-	+	+
Group 6	-	+	-
Group 7	-	-	+
Group 8	-	-	-

Five days following *Salmonella* challenge, half of the *Salmonella* challenged and half of the control broilers (n=40 each) will be placed on the experimental ozonated water setup in the nipple drinkers (developed and optimized in Task 2) with the remaining half allowed access to the normal nipple drinkers (control). Additionally, half of each pen of birds (n=20) will be randomly selected and subjected to feed withdrawal for 18 h; the remaining birds will continue to have free access to feed. After the 18 h, all birds will be euthanized and the crops and ceca will be collected and plated. A summary of the treatment groups is outlined in Table 5.

Crops will be collected by clamping across the pre and postcrop esophagi using a surgical Carmalt forcep and immersion in boiling water for 1 s to reduce external contamination of the crop. Previous experiments in Dr. Hargis' lab have demonstrated that immersion of crops or ceca in boiling water for 1 s effectively removed all detectable *S. enteritidis* from the surface of intentionally contaminated crops and ceca while not affecting recovery of *S. enteritidis* injected into the lumen of the tissues (data not shown). The crop will be sectioned aseptically below the clamp and the body of the crop, with the lumen and contents exposed, will be collected aseptically in individual Whirl-Pac bags. The ceca will be collected manually by dissection, clamped at the cecal neck, immersed in boiling water for 1 s, and the body of each cecum will be macerated and aseptically collected into sterile Whirl-Pac bags.

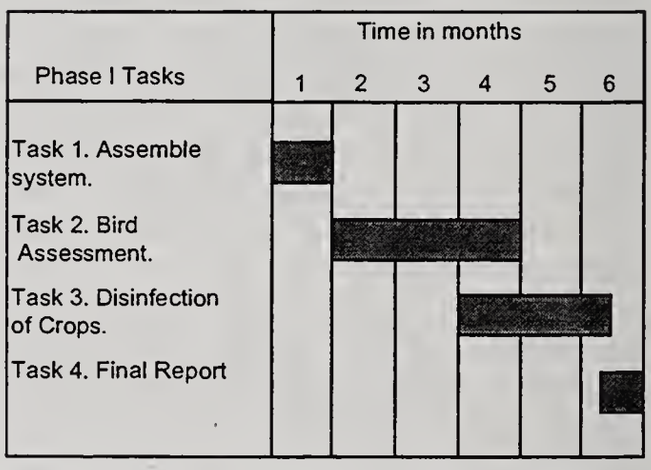

Figure 6 Milestone Chart for the Phase I Effort.

Following crop and ceca removal, 20 mL of tetrathionate broth base, No. 0104-17-6, will be added to each Whirl-Pac bag containing the samples. The samples will be stomached for 30 s and incubated for approximately 24 h at 37°C. Following this enrichment phase, each sample will be individually streaked on brilliant green agar, No. 0285-01-5, plates containing 25 µg novobiocin and 20 mg nalidixic acid/mL to prohibit growth of *Salmonella* other than the antibiotic-resistant challenge isolate. The plates will then be incubated for 24 h at 37°C, examined for the presence or absence of the antibiotic-resistant challenge isolate and enumerated.

A milestone chart plotting the expected progress of the Phase I effort is shown in Figure 6.

C6. RELATED EXPERIENCE

Dr. G. Duncan Hitchens

Dr. Hitchens (P.I., Vice President and Senior Research Scientist) has research and development expertise in both microbiology and ozone technology. Dr. Hitchens has a B.Sc. degree in microbiology and his Ph.D. was in microbial physiology. Dr. Hitchens has directed, or personally carried out, research in electrochemical reactor technology for ozone formation that is directly relevant to the proposed project area. Dr. Hitchens has carried out numerous studies on electrochemical ozone generation. This research has resulted in two patents: "Methods and Apparatus for Using Gas and Liquid Phase Cathodic Depolarizers" United States Patent No.: 5,770,033 and "Method and Apparatus for Electrochemical Production of Ozone", United States Patent No. 5,460,705. The electrochemical process is based on a SPE. A number of R&D projects on PEM water electrolyzers, water treatment devices and hydrogen/oxygen PEM fuel cells have been undertaken at Lynntech, Inc., under Dr. Hitchens' technical management. Since 1990, Dr. Hitchens has conducted or directed several microbiological-related projects. Some of these projects are summarized below.

Disinfection of Salmonella. This was investigated under a USDA contract (USDA Grant Agreement No.: 93-33610-8460). Utilizing an electrochemical ozone generation system, levels of *Salmonella* were reduced two log fold in commercial chicken hatchers using gaseous ozone. Bacteria levels on broiler carcass surfaces were also significantly reduced using ozonated solutions.

Electrochemically Based Modules for Sterilization In the Field. This was investigated for the US Army (Contract No.: DAMD17-91-C-1105). A pilot-scale system was designed, fabricated and tested which demonstrated the effectiveness of gaseous ozone for use as a rapid turn around sterilization method for field hospitals.

Ozone Decontamination and Treatment of Red Bag Medical Waste. A mobile pilot-scale treatment system for the disinfection of red bag waste was field-tested at Lackland AFB, Texas in 1998 for the U.S. Air Force (Contract No.: FY7624-96-C-2001). Gaseous ozone was the disinfectant.

Integrated On-Board Cleaning Process Using Ozone. (Contract No.: NAS9-19447) This contract involved an evaluation of the use of ozone as a cleaning agent and as a laundry disinfectant. A pilot-scale system is being readied for delivery to NASA's Johnson Space Center.

Ozone Sterilization Technique for Endoscopes. (Grant No.: 1R43 E507303) Under this grant, a series of laboratory tests demonstrated the efficacy and effectiveness of ozone as an endoscope disinfection-sterilization agent. The project is currently in Phase II start-up.

Dr. K. Scott McKenzie

Dr. McKenzie (Research Scientist) holds a Ph.D. in toxicology from Texas A&M University. His expertise is in the area of disinfection and oxidation methods for food and water decontamination. His background is very relevant to this project because much of the research he has conducted has involved electrochemical reactors for oxidant synthesis. For instance, Dr. McKenzie has been the lead scientist, first at TAMU and recently at Lynntech, on the use of gaseous ozone for the detoxification of aflatoxin-contaminated corn. This research has resulted in several

publications (see attached Resume). The unique aspect of the research was an electrochemical process was used for the generation of ozone. This reactor was similar in design to the solid polymer electrolyte (SPE) membrane cell described in this proposal. Dr. McKenzie is very familiar with the operation of electrosynthesis reactors for ozone and has first hand knowledge in the testing of these in food decontamination protocols.

Of particular importance to this project is Dr. McKenzie's past employment in a state of the art food processing facility as a production supervisor. During his management training period, he designed, executed and published in house studies that involved (i) identification (Hazard Analysis) of previously undescribed microbial sources of contamination (Critical Control Points) within the various portions of the plant, (ii) description of the extent of contamination from each source through product sampling and subsequent microbiological analysis, and (iii) design, layout and recommendation of intervention strategies to reduce surface contamination. His knowledge of HACCP coupled with his experience using electrochemically generated O_3 to remediate contaminated food and feed make him a key member of the research team.

Additional Technical Expertise

Technical expertise will also be provided by Jim Fyffe who received his B.S. from Texas A&M University in Bioenvironmental Engineering in 1996.

D. KEY PERSONNEL AND BIBLIOGRAPHY

(See Attached Resumes).

E. FACILITITES AND EQUIPMENT

The company occupies 27,000 ft^2 of space which includes general laboratory facilities, analytical chemistry lab, an electronics shop, a basic machining and fabrication facility and two high bay areas where scale-up hardware can be assembled for testing and evaluation. The equipment available to this project includes: LABCONCO Class II Biohazard Cabinet, model 36208-04, Precision Scientific Gravity Convection Incubator, Lab-Line Instruments Adjustable Speed Orbital Shaker, model 4625, Carl Zeis Compound Microscope, Tuttnauer / Brinkmann Autoclave, model number 2540E, Pipettemen, spreaders, burners, plates and various media. Also, Lynntech will be installing a Waters *Integrity* LC-MS system in September of 1998. Other apparatus includes: power supplies, potentiostats, X-Y recorders, a Varian, atomic absorption spectrophotometer, Model AA-875, a Shimadzu UV/Visible spectrophotometer, Model UV 2101 PC, a Dionex ion-chromatograph, Model DX-100 and a "Nanopure" ultrapure water system. In addition, standard laboratory equipment, such as glassware, pH-meters, voltmeters, balances, fume hoods and computers and computer network consisting of over 70 IBM and Macintosh personal computers are available. The Product Development area is equipped with CAD capabilities for developing comprehensive engineering drawings and

electronic schematics. Basic machining, drilling, metal cutting, bending and welding can be performed as needed. Numerous tools for mechanical assembly and testing are also available and Lynntech personnel fabricate all types of electrical wiring harnesses and connectors.

F. OUTSIDE SERVICES

Dr. Billy Hargis and Dr. David Caldwell will provide consulting as experts in the field of reduction and control of pathogens on poultry. Dr. Caldwell will assist with Tasks 3 objectives through retrofitting of the ozonation apparatus developed in Tasks 1 and 2 at a research broiler house currently under his supervision. Dr. Hargis will provide acquisition and gavaging of broilers and subsequent microbiological analysis of crop and cecal microbes in his laboratory. These studies will be conducted in part at the Poultry Science Center on the campus of Texas A&M University under the direct supervision of Professors Hargis and Caldwell, Departments of Poultry Science and Veterinary Pathobiology, Texas A&M University. Letters from Drs. Hargis and Caldwell acknowledging their collaborative arrangement and participation in this project are attached.

G. SATISFYING THE PUBLIC INTEREST

Salmonella contamination of broiler products is a continual problem for the poultry industry. With the phasing out of chlorine related products in the broiler cleaning phase there is more room for innovative technologies such as ozone generators to be used in their place. The GRAS status that ozone has places it in a strong position to dominate the food treatment industry. Lynntech's new technology will fill a gap that is missing in the current broiler treatment process allowing for greater removal of potential pathogenic species from the final store ready product. The improved quality of the product will ultimately be passed on to the consumer which can only benefit the poultry industry.

H. POTENTIAL POST APPLICATIONS

(I). Company Information

Lynntech, Inc., is a small business specializing in technology development. The company has a staff of 65 employees of which 23 are at the Ph.D. level. In addition to being successful in developing new concepts having federal government and industrial potential, we have a record of moving ideas from the laboratory proof-of-concept stage to the pilot scale hardware system. Research and development, testing, engineering design and fabrication are all performed in-house using our team of multi-disciplinary staff. Our small size permits high intensity efforts to be carried out in rapid succession.

The business objectives of Lynntech, Inc. have the development and commercialization of electrochemically based technologies for their foundation. The company has strong R&D capabilities in the area of electrochemical technologies. In addition to federal government grants and contracts, the company has secured R&D contracts from industrial corporations, and provides consulting services to private industry. Arising from previous and existing contracts, the company has acquired the services of key internationally renowned

consultants and developed subcontracting relationships with research centers at Texas A&M University.

(II). General Appraisal of the Marketplace

Ozone oxidation allows commercial entities, that need water purification, to use ozone more cost effectively as a purifying agent. The actual size of the water treatment markets are listed in Table 6.

Table 6. Potential Markets and Market Sizes for Ozone Based Technologies.

Potential Market	Market size
Water purifying/cleaning compounds	$267 million
Oxidizing and bleaching agents	$2.70 billion
Liquid detergents	$1.70 billion
Powder detergents	$2.20 billion
Sludge management	$1.98 billion
Industrial waste/wastewater	$4.53 billion
Municipal water/wastewater	$4.83 billion
Bottled water industry	$3.00 billion

The electrochemical ozone generator and a highly sensitive ozone monitor has implications in a wide variety of industries. Some of these industries are water treatment, electronics, pharmaceutical, food and beverage, environmental remediation and electricity generation. It can also be used to purify the water used in aquariums, laboratories, chemical processing, and laundry applications.

It is projected that this technology can be rapidly transferred to industrial and consumer-based products. No technical obstacles to commercial manufacturing and marketing are foreseen and Lynntech has developed a strategic partnership with Teledyne Water Pik to bring this technology to the market place. A world wide marketing survey made by Water Pik identified 5 major markets outside of the United States where new small scale, self-contained water treatment units have extensive market potential. The information gained from the Phase I research will have significant implications on the commercialization prospects of the ozone generator.

The commercialization efforts will be made during the second year of the Phase II. Initial patents will be submitted to establish intellectual property ownership which is essential for all subsequent steps in the commercialization plan. Lynntech, Inc., typically prosecutes between 5 and 10 patents per year using its internal resources. We will solicit interest from industry by disclosure of inventions (and experimental data) resulting from Phase II research; non-disclosure agreements will be used where appropriate. To accelerate the commercialization process, Lynntech has created the position of Manager, Marketing and Sales, within it's organizational structure in late 1996. This position has recently been filled by Thomas D. Rogers, who has a strong technical background and expertise in marketing and sales. Part of his role within the company will be to market SBIR developed technologies to various industrial concerns, government agencies and government prime contractors. Through his activities, securing Phase III follow-on funding commitments for SBIR projects will be greatly enhanced.

Lynntech has been, and is presently, aggressively pursuing a Phase III follow-on funding commitment for this project from interested industrial concerns. As of the time of writing this document, a Phase III commitment had not been secured. However, it is anticipated that such a commitment will be obtained either from one company, or a consortium of companies, over the next few months.

I. CURRENT AND PENDING SUPPORT

(No similar proposals have been submitted).

Resume: **DR. G. DUNCAN HITCHENS (SENIOR RESEARCH SCIENTIST)**

EDUCATION:

Ph.D.: Microbial Physiology; Department of Botany and Microbiology, University College of Wales, Aberystwyth, Wales (1985).

B.Sc.: Microbiology; Department of Botany and Microbiology, University, College of Wales, Aberystwyth, Wales (1981).

EMPLOYMENT:

Vice President, Lynntech, Inc., College Station, Texas, 1991-Present

Senior Scientist, Lynntech, Inc., College Station, Texas, 1989-91

Research Associate, Center for Electrochemical Systems and Hydrogen Research, Texas A&M University, College Station, Texas, 1988-89

Research Associate, Laboratory of Surface Electrochemistry, Department of Chemistry, Texas A&M University, College Station, Texas, 1985-88

PUBLICATIONS: 35 PRESENTATIONS & ABSTRACTS: 53 PATENTS: 4

SELECTED PUBLICATIONS:

G.D. Hitchens, D.B. Kell, J.G. Morris (1982) "Transmembrane Respiration-driven H^+-Translocation is Unimposed in an eup Mutant of *Escherichia coli*". *J. Gen. Microbiol.* **128**, 2207.

G.D. Hitchens (1989) "Electrode Surface Microstructures in Studies of Biological Electron Transfer". *Trends Biochem. Sci.* **14**, 152.

O.J. Murphy, G.D. Hitchens, L. Kaba and C.E. Verostko (1992) "Direct Electrochemical Oxidation of Organics for Waste Water Treatment". *Water Research.* **26** 443.

T.D. Rogers, G. D. Hitchens, C. E. Salinas, O.J. Murphy, H.W. Whitford, (1992) "Water Purification, Microbiological Control, Sterilization and Organic Waste Decomposition Using an Electrochemical Advanced Ozonation Process". *J. Aerospace* **101** 786.

T.D. Rogers, G.D. Hitchens, S.K. Mishra and D.L. Pierson, (1992) "Microelectrode-Based Technology for the Detection of Low Levels of Bacteria". *J. Aerospace* **101** 795.

G.D. Hitchens, D. Hodko, D.R. Miller, O.J. Murphy and T.D. Rogers, (1993) "Bacterial Activity Measurements by Mediated Amperometry in a Flow Injection System". *Russian Journal of Electrochemistry* **29** 1344 (*Elektrokhimiya* **29** 1527).

K.S. McKenzie, L.F. Kubena, A.J. Denvir, T.D. Rogers, G.D. Hitchens, R.H. Bailey, R.B. Harvey, S.F. Buckley and T.D. Phillips (1997) "Degradation of Aflatoxin B_1 and Prevention of Aflatoxicosis in Turkey Poults by Treatment of Field-Contaminated Corn with a Novel Source of Ozone" Poultry Science (submitted).

SELECTED PRESENTATIONS AND ABSTRACTS:

"Water Purification, Microbiological Control, Sterilization and Organic Waste Decomposition Using an Electrochemical Advanced Ozonation Process". SAE Technical Paper 921234, 22nd International Conference on Environmental Systems, Seattle, WA July 13-16 (presented by T. Rogers)

"Aflatoxicosis in Turkey Poults is Prevented by Treatment of Field-Contaminated Corn with a Novel Source of Ozone". K.S. McKenzie, L.F. Kubena, A.J. Denvir, T.D. Rogers, G.D. Hitchens, R.H. Bailey, R.B. Harvey, S.A. Buckley and T.D. Phillips, (abstract) Poultry Science Supp. 12 (1997).

"Disinfection and Sterilization using Electrochemically Generated Ozone". G.D. Hitchens, T.D. Rogers and C.C. Andrews, South Texas Section of the Electrochemical Society, June 14 (1997) Texas A&M University, College Station, TX.

SELECTED REPORTS:

T.D. Rogers, C.L. Sheffield, K.C. Anderson, G.D. Hitchens, and O. J. Murphy "A New Disinfection Technique for Commercial Poultry Facilities" Final Technical Report USDA Small Business Innovation Research Phase I Award February (1994).

G.D. Hitchens, T.C. Allen, T.D. Rogers, L.B. Sexton, J. Cantu and K.C. Anderson, "Electrochemically-Based Modules for Sterilization in the Field" Final Report US Army Medical Research and Materiel Command, Contract No.: DAMD17-91-C-1105, September (1995).

Resume: **DR. K. SCOTT MCKENZIE**

EDUCATION:

Ph.D.: Toxicology, Texas A&M University, (1993-1997)

B.S. : Biomedical Science, College of Veterinary Medicine, Texas A&M University (1987-1991) Animal Science, College of Agriculture and Life Sciences, Texas A&M University (1987-1991)

EMPLOYMENT:

Research Scientist, Lynntech, Inc., College Station, Texas, 1997 to present.

Graduate Research Assistant, Faculty of Toxicology, Department of Veterinary Public Health, Texas A&M University, 1993-1997.

Production Supervisor, Cargill Corp., EXCEL Division, Fort Morgan, Colorado, 1991-1993.

SELECTED PUBLICATIONS: Johnson, L, McKenzie, K.S. and Snell, J.R. (1996) Partial wave in human seminiferous tubules appears to be a random occurrence. *Tissue and Cell* **28**(2), 127-136.

McKenzie, K.S., Sarr, A.B., Mayura, K., Bailey, R.H., Miller, D.R., Rogers, T.D., Norred, W.P., Voss, K.A. Plattner, R.D. and Phillips, T.D. (1997) Chemical degradation of diverse mycotoxins using a novel method of ozone production. *Food and Chemical Toxicology* **35**, 807-820.

Mayura, K., Abdel-Wahhab, M.A., McKenzie, K.S., Sarr, A.B., Edwards, J.F., Naguib, K., and Phillips, T.D. (1998) Prevention of maternal and developmental toxicity in rats via dietary inclusion of common aflatoxin sorbents: Potential for hidden risks. *Toxicological Sciences* **41**(2), 175-182.

McKenzie, K.S., Kubena, L.F., Denvir, A.J., Rogers, T.D., Hitchens, G.D., Bailey, R.H., Harvey, R.B., Buckley, S.F. and Phillips, T.D. (1998) Aflatoxicosis in turkey poults is prevented by treatment of naturally contaminated corn with ozone generated by electrolysis. *Poultry Science* (in press).

Mayura, K., Huebner, H.J., Dwyer, M.R., McKenzie, K.S., Donnelly, K.C., Kubena, L.F., Phillips, T.D. (1998) Assessment of the potency of crude coal tar and fractionated mixtures utilizing the chick embryotoxicity screening test and the *Salmonella* / microsome bioassay. *Chemosphere* (in press).

Lemke, S.L., Mayura, K., Ottinger, S.E., McKenzie, K.S., Wang, N., Fickey, C., Kubena, L.F. and Phillips, T.D. (1998) "Assessment of the estrogenic effects of zearalenone after treatment with ozone utilizing the mouse uterine weight bioassay." *J. Toxicology and Environmental Health* (submitted).

McKenzie, K.S., Lemke, S.L., Denvir, A.J., Rogers, T.D., Hitchens, G.D., Kubena, L.F. and Phillips, T.D. (1998). Identification of aflatoxin B_1 oxidation products after treatment with aqueous ozone. *Agricultural and Food Chemistry* (in preparation).

TECHNICAL REPORTS:

Denvir, A.J., Rogers, T.D., Hitchens, G.D., McKenzie, K.S., Phillips, T.D. and Kubena, L.F. "Destruction of aflatoxins in grain using gaseous ozone." Final Report. USDA-SBIR Grant 95-33610-1429. Dec, 1996.

McKenzie, K.S., Denvir, A.J., Rogers, T.D., Hitchens, G.D., Williams, J.J., Carstens, G.E., and Byers, F.M. "Ozone conversion of low quality feed stocks to high energy feed." Final Report. USDA-SBIR Grant 97-33610-4071. Dec.,1997.

ABSTRACTS:

McKenzie, K.S., Sarr, A.B., Bailey, R.H., Miller, D.R., Kubena, L. and Phillips, T.D. (1995) Oxidative degradation of aflatoxins using a novel method of ozone production. *The Toxicologist* **15**(1), 215.

McKenzie, K.S., Sarr, A.B., Mayura, K., Norred, W.P., Voss, K.A., Plattner, R.D., Rogers, T.D. and Phillips, T.D. (1996) Degradation and toxicological evaluation of fumonisin B_1 and other mycotoxins treated with hydrolytically-produced ozone gas (abstract) *The Toxicologist* **30**(1), 213.

McKenzie, K.S., Denvir, A.J., Rogers, T.D., Kubena, L.F., Mayura, K., Dwyer, M.R. and Phillips, T.D. (1997) Toxicity and degradation of aflatoxin B_1 in field contaminated corn treated with electrolytically-generated ozone gas. (abstract) *The Toxicologist* **36**(1), 40.

McKenzie, K.S., Kubena, L.F., Denvir, A.J., Rogers, T.D., Hitchens, G.D., Bailey, R.H., Harvey, R.B., Buckley, S.F. and Phillips, T.D. (1997) Aflatoxicosis in turkey poults is prevented by treatment of field-contaminated corn with a novel source of ozone (abstract) *Poultry Science Suppl.* (12) 1997.

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Education:

B.S.	*University of Minnesota*	1980	D.V.M.	*University of Minnesota*	1986
M.S.	*University of Georgia*	1983	Ph.D.	*University of Minnesota*	1987

Professional Organizations and Honors:

American College of Poultry Veterinarians (Diplomate) **1992**-Present
Poultry Science Association & American Veterinary Medical Association
Texas Veterinary Medical Association
Carrington Laboratories Faculty Award for "Outstanding Research Program in Cell Biology" (**1991**)
Texas Poultry Improvement Board: Advisor (**1990**-Present)
Poultry Disease Diagnostic Laboratory: "Director" (**1987** - Discontinued September 1, 1991)
Recipient of the 1993 Poultry Science Association Research Award
Recipient of USDA/ARS Certificate of Merit for Scientific Leadership **1994**
Center for Food Safety Member (**1995**-Present)
Vice President, Southern Poultry Science Society, **1996-1997**
President, Southern Poultry Science Society, **1998**
The **1998** National Broiler Council Research Award, Poultry Science Association

Selected Recent and Relevant Publications:

Barnhart, E.T., D.J. Caldwell, M.C. Crouch, J. A. Byrd, D.E. Corrier, and B.M. Hargis, 1998. Evaluation of Potential Disinfectants for Pre-Slaughter Broiler Crop Decontamination. Poultry Sci. (submitted).

Sarlin, L.L., Barnhart, E.T., Moore, R.W., Corrier, D.E., Stanker, L.H., and Hargis,B.M., 1998. Comparison of Enrichment Methods for Recovery and Chick Infectivity of Chlorine-Injured *Salmonella enteritidis*. J.Food Protection. (in press).

Sarlin, L.L., Barnhart, E.T., Caldwell, D.J., Moore, R.W., Byrd, J.A., Caldwell, D.Y., Corrier, D.E., DeLoach, J.R., and Hargis,B.M., 1998. Evaluation of Alternative Sampling Methods for *Samonella* Critical Control Point Determination at Broiler Processing. Poultry Sci. (submitted).

Barnhart, E.T., D.J. Caldwell, M.C. Crouch, J. A. Byrd, D.E. Corrier, and B.M. Hargis, 1998. Effect of Lactose Administration in Drinking Water Prior to and During Feed Withdrawal on *Salmonella* Recovery From Broiler Crops and Ceca. Poultry Sci. (submitted).

G. A. Ramirez, L. L. Sarlin, D. J. Caldwell, C. R. Yezak, Jr., M. E. Hume, E. E. Corrier, J. R. DeLoach and B. M. Hargis (1997) Effect of Feed Withdrawal on the Incidence of *Salmonella* in the Crops and Ceca of Market Age Broiler Chickens. Poultry Science. 76: 654-656.

Kogut M., Tellez G., McGruder E., Hargis B., DeLoach J. (1997) Immunoprophylaxis of *Salmonella gallinarum* infection by Salmonella enteritidis-immune lymphokines in broiler chicks. [Clinical Trial. Journal Article. Randomized Controlled Trial] Advances in Experimental Medicine & Biology. 412:413-20, 1997.

Audrey P. McElroy, Noah D. Cohen and Billy M. Hargis (1996) Evaluation of the Polymerase Chain Reaction for the Detection of *Salmonella enteritidis* in Experimentally Inoculated Eggs and Eggs from Experimentally Challenged Hens. Journal of Food Protection. 59 (12): 1273-1278.

M. D. de Icaza, G. T. Isaias, G. Expinosa, B.M. Hargis (1996) Competitive Exclusion Between *Salmonella enteritidis* and *Salmonella gallinarum* in One-Day-Old Broiler Chicken Challenged Consecutive-Or Simultaneously. Proc. Veterinaria Mexico. 27: 295-298.

Hargis, B.M., Caldwell, D.J., Brewer, R.L., Corrier, D.E. and Deloach, J.R. (1995) Evaluation of the chicken crop as a source of *Salmonella* contamination for broiler carcasses. Poulty Sci. 74:1548-1552

Corrier, D.E., Nisbet, D.J., Scanlan, C.M., Hollister, A.G., Caldwell, D.J., Thomas, L.A. Hargis, B.M., Tompkins, T. and DeLoach, J.R. (1995) Treatment of commercial broiler chickens with a characterized culture of cecal bacteria to reduce *Salmonellae* colonization. Poultry Science, 74:1093-1101.

Resume: **DAVID J. CALDWELL**

Education: B.S (Poultry Science) Texas A&M University, 1991
M.S. (Veterinary Microbiology) Texas A&M University, 1994
Ph.D. (Veterinary Microbiology) Texas A&M University, 1997

Title: Assistant Professor, Departments of Poultry Science, College of Agriculture and Life Sciences, and Veterinary Pathobiology, College of Veterinary Medicine, Texas A&M University

Professional Organizations:

-American Association for the Advancement of Science
-World's Poultry Science Association
-American Association of Veterinary Immunologists
-Poultry Science Association
-Society for Leukocyte Biology
-The American Society for Microbiology

Selected Scientific Publications:

Caldwell, D.J.., B.M. Bargis, D.E. Comer, J.D. Williams, L. Vidal, and l.R. DeLoach, 1994. Predictive value of multiple drag-swab sampling for the detection of *Salmonella* from occupied or vacant houses. *Avian Vis.* 38:461-466.

Caldwell, D.J., B.M. Bargis, D.E. Comer, L. Vidal, and l.R. DeLoach, 1995. Evaluation of persistence and distribution of *Salmonella* serotype isolation from poultry farms using drag-swab sampling. *Avian Vis.* 39:617-621.

Comer, D.E., D.J. Nisbet, C.M. Scanlan, A.G. Bollister, D.l. Caldwell, L.A. Thomas, B.M. Bargis, T. Tompkins, and l.R. DeLoach, 1995. Treatment of commercial broiler chickens with a characterized culture of cecal bacteria to reduce salmonellae colonization. *P oultry Sci.* 74: 1093-1101.

Bargis, B.M., D.J. Caldwell, R.L. Brewer, D.E. Comer, and l.R. DeLoach, 1995. Evaluation of the chicken crop as a source of *Salmonella* contamination for broiler carcasses. *Poultry Sci.* 74: 1548- 1552.

Ramirez, G.A., L.L. Sarlin, D.J.. Caldwell, C.R. Yezak, lr., M.E. Bume, D.E. Comer, l.R. DeLoach, and B.M. Bargis, 1997. Effect of feed withdrawal on the incidence of *Salmonella* in the crops and ceca of market-age broiler chickens. *Poultry Sci.* 76:654-656.

Caldwell, D.J., B.M. Bargis, D.E. Comer, and l.R. DeLoach, 1997. Frequency of isolation of *Salmonella* from protective foot covers worn in broiler houses as compared to drag-swab sampling. *Avian Vis.* 42:381-384.

Bargis, B.M., and D.J. Caldwell, 1997. Evidence for an endocrine role for the chicken humoral immune system. *Rev. Poultry Sci.* (in press).

Bargis, B.M., D.J. Caldwell, and M.B. Kogut, 1997. Immunoprophylaxis of poultry against *Salmonella enteritidis in: Salmonella enteritidis* in humans and animals. A.M. Saeed, ed. Iowa State University Press, Ames, lA.

Sarlin, L.L., E.T. Bamhart, D.J. Caldwell, R.W. Moore, J.A. Byrd, D.Y. Caldwell, D.E. Comer, J.R. DeLoach, and B.M. Hargis, 1998. Evaluation of alternative sampling methods for *salmonella* critical control point detennination at broiler processing. *Poultry Sci.* (submitted).

Bamhart, E.T., D.J. Caldwell, M.C. Crouch, J. A. Byrd, D.E. Comer, and B.M. Hargis, 1998. Effect of lactose administration in drinking water prior to and during feed withdrawal on *salmonella* recovery from broiler crops and ceca. *Poultry Sci.* (submitted).

Caldwell, D.J., C.E. Dean, A.P. McElroy, J.G. Manning, D.Y. Caldwell, J.A. Byrd, and B.M. Bargis, 1998. Bursal anti-steroidogenic peptide (BASP): modulation of mitogen-stimulated bursal- lymphocyte DNA synthesis. *Comp. Biochem. Physiol.* (submitted).

Caldwell, D.J., and B.M. Hargis, 1998. BASP-induced suppression of mitogenesis in chicken, rat, and human PBL. D*ev. Comp. lmmunol.* (in press).

REFERENCES

Andreozzi R, Caprio V. and D' Amore M. G., (1995) *Wat. Res.*, 29, 1: 1.

Androsov. S., Eremina, L., Nikolaev, N., Sarantzev, B., and Maslennikov, O., (1998), Ozone in Medicine, 2nd International Symposium on Ozone Applications, March 24-26, 1997, Havana, Cuba.

Anon, (1997a) EPRI Journal, July/August 22:6-15.

Anon , (1997b) Wired Magazine, December (1997) 159.

Barnhart, E.T., D.J. Caldwell, M.C. Crouch, J. A. Byrd, D.E. Corrier, and B.M. Hargis, (1998a) Evaluation of Potential Disinfectants for Pre-Slaughter Broiler Crop Decontamination. Poultry Sci. (submitted).

Barnhart, E.T., D.J. Caldwell, M.C. Crouch, J. A. Byrd, D.E. Corrier, and B.M. Hargis, (1998b) Effect of Lactose Administration in Drinking Water Prior to and During Feed Withdrawal on *Salmonella* Recovery From Broiler Crops and Ceca. Poultry Sci. (submitted).

Byrd, J. A., D. E. Corrier, R. H. Bailey, D. J. Nesbet & L. H. Stanker (1998). Effect of a competitive exclusion product on colonization of Salmonella typhimurium Definitive Phage 104 in market-age broiler chickens. Poultry Science (Submitted).

Campbell, D.F., R.W. Johnson, G.S. Campbell, D. McClain, and J.F. Macaluso (1983) Poultry Sci. 62:437-444

Chang, Y.H. and Sheldon, B.W.,(1989), Poultry Sci. 68: 1078.

Corrier, D.E., B. M. Hargis, A. Hinton, Jr., D. Lindsey, D. Caldwell, J. Manning and J.R. DeLoach, (1990) Avian Dis., 35:337-343.

Dickson, J.S. and Anderson, M.E., (1992), J Food Protec.55: 133.

Easton, T. Austral.,(1951), J. Dairy Tech. 4: 142.

Fanelli, M.J., W.W. Sadler, C.E. Franti and J.R. Brownell (1971) Avian Dis., 35: 366-395.

Federal Register, Food and Drug Administration, April 17, (1997).

Fillippi A., (1997), Ozone Science and Eng., 19: 387.

Foller P. C., (1982), J. Electrochem. Soc., 129: 506.

Graham, D.M., (1997) Food Technology, 55:6-15.

Hargis, B.M., D.J. Caldwell, R.L. Brewer, D.E. Corrier and J.R. Deloach, (1995) Poultry Sci., 74:1548-1552.

Hitchens, G.D., T.D. Rogers, C.L. Sheffield, K.C. Anderson, and C.E. Salinas, (1994) In: Water Purification by Photocatalytic, Photoelectrochemical, and Electro-chemical Processes (eds. T.L. Rose, E. Rudd, O. J. Murphy and B.E. Conway) p.204, The Electrochemical Society, Pennington, New Jersey.

Humphrey, T.J., A Baskerville, A. Witehead, B. Rowe and A. Henley (1993) Vet. Rec. 132:407-409.

Jacobs-Reitsma, W.F., N.M. Bolder and R.W.A.W. Mulder (1994) Poultry Sci. 73:1260-1266.

Lahellec, C., and P. Collin (1985) Br. Poultry Sci. 26: 179-186.

Lammerding, A.M., M.M. Garcia, E.D. Mann, Y. Robinson, W.J. Dorward, R.B. Truscott and F. Tittiger (1988) J. Food Protec. 51:47-52.

Langlais, B., D. A. Reckhow, D. A., and Bader, H, (1991), "Ozone in Water Treatment Application and Engineering" Lewis Publications.

Lillard H.S., (1989) J. Food Prot., 52:829-832.

Majchrowicz, A., (1998) Agricultural Outlook, June July/AGO-252:13-15.

Marinescu, M., B. Fetsy, R. Derimay, and F. Megraud (1987) Eur. J. Clin. Microbiol. 6:693-695.

May, D. J., Lott, B. D., and Simmons J. D., (1997), Poultry Sci., 76:944-947.

Mulder, R.W.A.W., (1995) J. Food Safety 15:239-246.

Murphy, O.J., C.E. Salinas, K.C. Anderson, M. Novak and G.D. Hitchens, (1994) In: Water Purification by Photocatalytic, Photoelectrochemical, and Electro-chemical Processes (eds. T.L. Rose, E. Rudd, O. J. Murphy and B.E. Conway) p.132, The Electrochemical Society, Pennington, New Jersey.

Murphy, O.J. and G.D. Hitchens (1995) "Method and Apparatus for Electrochemical Production of Ozone", United States Patent No.: 5,460,705

Murphy, O.J. and G.D. Hitchens (1998) "Methods and Apparatus for using Gas and Liquid Phase Cathodic Depolarizers" United States Patent No.: 5,770,033.

Nebel, C., and W.W. Nezgod (1984) Solid State Technol., 27:185.

Ramirez, G.A., L.L. Sarlin, D.J. Caldwell. C.R. Yezak, Jr., M.E. Hume, D.E. Corrier, J.R. Deloach and B.M. Hargis, (1997) Poultry Sci., 76:654-656.

Rilling, S., and Veibahn, R., (1987),"The use of Ozone in Medicine" Haug, New York.

Sarig, P., Zahavi, T., Zutkhi, Y.,Yannai, S., Lisher, N., and Ben-Arie, R. (1996) Physiol. Molec. Plant Pathol. 48: 403.

Shuen Shen Y and Ku Y.,(1995), Wat. Res., 29, 1: 1.

Silva, L. and Wong, R., (1998), Ozone in Medicine, 2nd International Symposium on Ozone Applications, March 24-26, Havana, Cuba.

Snoeyenbos, G.H., A.S. Soerjadi, and O.M. Weinak, (1982) Avian Dis. 26:566-575

Stern, N.J. and J.E. Line (1992) J. Food Prot. 55:663-666.

Sunnen, G. V., (1987),"The use of Ozone in Medicine" Haug, New York.

Takahashi N and Nakai T., (1994), Wat. Res., 28, 7: 1563.

Turk, R., (1985), Ozonachrichten: 461.

Yang, P.P.W. and Chen, T.C., (1979)a, J. Food Sci. 44: 501.

Yang, P.P.W. and Chen, T.C., (1979)b, J. Food Process. Preserv. 3: 177.

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August 28, 1998

Dr. Scott McKenzie
Lynntech, Inc.
7610 Eastmark Dr., Ste. 105
College Station, TX 77840

Dear Dr. McKenzie:

As per our discussions during the last several months, I am pleased to assist and provide advise as needed for your project under development for consideration by USDA/SBIR involving control of orally-transmitted infectious and zoonotic diseases using electrochemically-generated ozone in drinking water. Recently, our laboratory has demonstrated that feed withdrawal is associated with tremendous increases in contamination of the upper gastrointestinal tract of chickens with important human pathogens such as *Salmonella*, *Campylobacter* and *E. coli* and that this area of the intestinal tract is critical for control of contamination of commercially processed poultry carcasses. In addition to potential reductions in these contaminants important to food safety, we should expect that effective concentrations of ozone may reduce bird-to-bird transmission of infectious agents important to production efficiency and poultry health. Based on comparative research, it would also appear that this technology may indeed provide an attractive and effective solution to these problems.

As we discussed, my laboratory is prepared to offer you any and all technical assistance that you may require in these investigations. We are experienced with research investigations relating to disinfection of drinking water and have available marked strains of *Salmonella*, *Campylobacter* and *Listeria* for your use. As we discussed, I can offer you access to our experimental poultry facilities at the Texas A&M University Poultry Science Research Center and can assist you with field research endeavors with several commercial poultry companies. I enthusiastically support your efforts in this area and am anxious to begin this cooperative effort.

Sincerely,

B.M. Hargis, DVM, PhD
Professor

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Room 101 Kleberg Animal and Food Science Center
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September 2, 1998

Dr. K. Scott McKenzie
Lynntech, Inc.
7610 Eastmark Drive, Suite 105
College Station, TX 77843

Dear Dr. McKenzie

I am writing this letter to confirm my willingness to serve as a collaborator and research team member on your USDA/SBIR proposal entitled "A New Technique for Ante-Mortem Control of Pathogens in Broilers". The extent and severity of *Salmonella* and *Campylobacter* contamination in the broiler industry, especially during feed withdrawal, has mandated the development of new technologies for pathogen reduction. The use of ozone in the drinking water of market broilers should provide an environmentally friendly alternative to other intervention methods and should compliment current approaches to pathogen control.

I can provide research facilities at the Texas A&M University Poultry Science Center for the Task 2 studies involving water consumption of ozonated water as outlined in the Proposal. I am looking forward to working with Lynntech on this project and hope your proposal meets with successful reviews.

Sincerely,

David J. Caldwell, Ph.D.
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Veterinary Pathobiology
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